

Agency for Healthcare Research and Quality Center for Quality Improvement and Patient Safety

Longitudinal Program Evaluation of the HHS Action Plan to Prevent Healthcare-Associated Infections

Year 1 Report

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LIST OF ABBREVIATIONS

ABCs	Active Bacterial Core Surveillance
AHRQ	Agency for Healthcare Research and Quality
APIC	Association of Professionals in Infection Control
ARRA	American Reinvestment and Recovery Act of 2009
ASH	Assistant Secretary for Health
ASPA	Assistant Secretary for Public Affairs
ASPE	Assistant Secretary for Planning and Evaluation
CAUTI	Catheter-associated urinary tract infection
CDC	Centers for Disease Control and Prevention
CDI	<i>Clostridium difficile</i> infection
CLABSI	Central line-associated bloodstream infection
CMS	Centers for Medicare & Medicaid Services
CoP	Condition of Participation
CU	Consumers Union
EHR	Electronic health record
FDA	Food and Drug Administration
FHISE	Federal Health Information Sharing Environment
GAO	Government Accountability Office
HAC	Hospital-acquired condition
HAI	Healthcare-associated infection
HCUP	Healthcare Cost and Utilization Project (AHRQ)
HHS	Department of Health and Human Services
HICPAC	Healthcare Infection Control Practices Advisory Committee
HRSA	Health Resources and Services Administration
ICD-9	International Classification of Diseases, Ninth Revision
IHI	Institute for Healthcare Improvement
IHS	Indian Health Service
IDSA	Infectious Diseases Society of America
MDRO	Multidrug-resistant organism
MPSMS	Medicare Patient Safety Monitoring System
MRSA	Methicillin-resistant <i>Staphylococcus aureus</i>
NHIN	Nationwide Health Information Network
NHSN	National Healthcare Safety Network
NIAID	National Institute of Allergy and Infectious Diseases
NIH	National Institutes of Health
NNIS	National Nosocomial Infections Surveillance System
ONC	Office of the National Coordinator for Health Information Technology
OHQ	Office of Healthcare Quality
OPHS	Office of Public Health and Science
POA	Present on admission
PSO	Patient Safety Organization

QIO	Quality Improvement Organization
SCIP	Surgical Care Improvement Project
SHEA	Society for Healthcare Epidemiology of America
SSI	Surgical site infection
VAP	Ventilator-associated pneumonia
VBP	Value-Based Purchasing
VHA	Veterans Health Administration

EXECUTIVE SUMMARY

Overview of the Evaluation

The National Evaluation of the Department of Health and Human Services' (HHS) Action Plan to Prevent Healthcare-Associated Infections is a large-scale formative evaluation project, designed to generate strategic insights across stakeholders. Conducted by IMPAQ International and the RAND Corporation (the IMPAQ/RAND team), the evaluation seeks to:

1. Record the content and scope of the Action Plan to Prevent Healthcare-Associated Infections (hereafter referred to as "Action Plan") including its current design and recorded progress;
2. Establish baseline data and provide feedback on how to strengthen ongoing assessments of the scope of healthcare-associated infections (HAIs) and interventions, how to reduce HAIs, and how to begin to understand the effectiveness of those interventions; and
3. Provide strategic insights from ongoing processes and outcomes regarding opportunities to reduce HAIs.

This evaluation is guided by the Context-Input-Process-Product (CIPP) model, which is a well-established, valid approach for studying and informing decision-making as part of large-scale, formative evaluation. To meet the objectives of the national evaluation, IMPAQ/RAND studied four key factors:

1. The **Context (C)** in which the Action Plan began;
2. The **Inputs (I)** considered and initiated to allow the Action Plan to develop;
3. The **Processes (P)** associated with implementing Action Plan-related efforts; and
4. The **Products (P)** and outcomes of these activities.

This report presents the results of the first year of the IMPAQ/RAND team's evaluation, which focused on assessing the Context and Input. Future years will assess Processes associated with the Action Plan and resulting Products.

The HHS Action Plan to Prevent Healthcare-Associated Infections

In 2008, the HHS Steering Committee for the Prevention of Healthcare-Associated Infections was established and charged with developing a comprehensive strategy to prevent and reduce HAIs. As a result of this mandate, in June 2009 HHS issued the Action Plan to Prevent Healthcare-Associated Infections, which established national goals for HAI prevention, including key actions for achieving identified short- and long-term objectives. The Action Plan is intended to enhance collaboration with external stakeholders and to strengthen the coordination and

impact of national efforts. The Office of Healthcare Quality (OHQ), established by the Assistant Secretary for Health in December 2009, coordinates the HHS Steering Committee responsible for implementation of the Action Plan. OHQ is located within OPHS, under the Office of the Secretary in the U.S. Department of Health and Human Services. The following HHS agencies were signatories to the published Action Plan: Agency for Healthcare Research and Quality (AHRQ); Office of the Assistant Secretary for Public Affairs (ASPA); Office of the Assistant Secretary for Planning and Evaluation (ASPE); Centers for Disease Control and Prevention (CDC); Centers for Medicare & Medicaid Services (CMS); Food and Drug Administration (FDA); National Institutes of Health (NIH); Office of the National Coordinator for Health Information Technology (ONC); and the Office of Public Health and Science (OPHS).

The Action Plan is a comprehensive, living document that describes the critical issues related to HAIs, specifies strategies to address those issues, and identifies targets for reducing HAIs over the next 5 years. It is organized in sections that cover such topics as metrics and targets, research, information systems and technology, incentives and oversight, outreach and messaging, and coordination and evaluation. These areas were developed and are guided by working groups.

Five working groups met during the first year to deliberate on current knowledge, research needs, and ways to prevent HAIs. The groups were charged with establishing roadmaps to meet the objectives of the Action Plan, monitoring progress toward those objectives, and updating the plan as needed.

The Action Plan, therefore, sets the framework for the current evaluation effort. It identifies the objectives and strategies to achieve the plan's goals, on which the IMPAQ/RAND team based the CIPP evaluation. In this report, we document the context that led to the development and release of the Action Plan as well as the critical inputs to it.

Methods for the Context and Input Evaluations

During Year 1, we conducted a document and literature review and interviews with key stakeholders to gain information about (1) the context in which the Action Plan was developed, and (2) the specific inputs to the Action Plan. The document and literature review provided us with factual information about context and inputs, while the key informant interviews enriched these data by giving us detailed information regarding the perceptions and experiences of stakeholders who were involved in developing the Action Plan. Many of these stakeholders will also be responsible for implementing the plan, which will provide initial insight into the Process component of the CIPP evaluation framework as well.

The goal of the document and literature review was to identify documents that might inform the Context and Input evaluations. We included three types of documents: (1) the most relevant documents that provided important historical context to understand catalysts for the Action Plan; (2) all documents that played a direct role in its development; and (3) documents produced as a result of Action Plan-related activities. This third set of documents will carry over

to the Process evaluation component of this project. In total, we identified and reviewed 30 journal articles, 78 internal organizational documents, and 113 published reports and other publicly available materials.

The IMPAQ/Rand team conducted informant interviews with a sample of participants. The interviews were intended to supplement the document review and offer a broad perspective on issues related to the context of the Action Plan's development. Consistent with a formative evaluation, our goal in developing the sampling frame was to generate a sample that could provide a range of perspectives from stakeholders engaged with the Action Plan. The sampling frame and the interview protocols were designed to capture both mainstream and alternative viewpoints for consideration. In total, 27 individuals were interviewed.

In addition to presenting the results of the document review and key stakeholder interviews, we draw relevant implications from the Baseline Data Inventory, also produced by the IMPAQ/RAND team, whose methods and results are detailed in a separate report.

Context Evaluation Results

In the Context evaluation, we report the perspectives of Federal agency officials and other stakeholders. We obtained these from our interviews and supplemented them with information gathered from reviews of the literature and other documents. Both sources of data were used to provide a high-level perspective on the forces and events that led to the creation of the Action Plan and helped form the requirements and expectations that guide the Action Plan and by which it will be judged by those responsible for oversight and by its varied stakeholders. The evaluation is provided in descriptive terms and also in evaluative terms using criteria of adherence to the goals of policy makers and stakeholders and the development of a well-coordinated gap-free approach in which logical requirements for transitioning from goals towards inputs, processes, and products are outlined. Where possible, comparisons with other programs and with the scientific literature are made. The context results are organized around three themes: (1) evaluation antecedents and catalysts of the Action Plan; (2) legislative oversight, funding, and regulatory expectations; and (3) policy mandates and expectations.

Evaluation Antecedents: Three Historical Forces Created Impetus for the Action Plan

Three historical forces operating prior to the development of the Action Plan were (1) the actions and activities of the epidemiological and infection control communities, (2) consumer advocates, and (3) the patient safety and improvement movement. These forces culminated in an event that was widely recognized as the catalyst for the development of the Action Plan—the publication in March 2008 by the Government Accountability Office (GAO) of a the congressionally mandated report *Health-Care-Associated Infections in Hospitals: Leadership Needed from HHS to Prioritize Prevention Practices and Improve Data on These Infections*.¹ The subsequent Congressional hearings related to the GAO findings set the stage for change within HHS and resulted in policy and funding to support the Action Plan.

Legislative and Regulatory Developments Shaped the Funding Environment and Expectations for the Action Plan

The Action Plan's development has been shaped, supported, and funded through a variety of legislative and regulatory policies at the Federal level. As programs and projects related to the Action Plan have been funded, primary Congressional oversight for activities related to the plan has moved from the House Oversight and Government Reform Committee to the House Appropriations Committee.

In the Omnibus Appropriations Act of 2009, Congress appropriated \$5 million to HHS to develop the Action Plan, with continued annual appropriations to support its coordination, particularly by OPHS. Omnibus appropriations also continue to support the HAI-related work of the Centers for Disease Control and Prevention (CDC) (in epidemiological research, development of prevention guidelines, and data collection systems) and of the Agency for Healthcare Research and Quality (AHRQ) (in implementation research and dissemination of HAI prevention practices). In addition, Congress made a substantial investment through the American Reinvestment and Recovery Act (ARRA) of 2009, which included \$50 million for HAI prevention to be spent over 2 years. Of this funding, \$10 million went to the Centers for Medicare & Medicaid Services (CMS) to improve inspections of ambulatory surgical centers, and \$40 million went to CDC for grants to States to improve statewide infrastructure, surveillance, and collaborative efforts for HAI prevention.

A number of other specific legislative and regulatory changes have focused on HAI-related activities. Key CMS programs targeted by these policies include the Conditions of Participation (CoP) for hospitals participating in Medicare, the emerging system for Value-Based Purchasing (VBP), and the 9th Statement of Work (SOW) for Quality Improvement Organizations (QIOs), funded by CMS to assist Medicare-reimbursed health care organizations improve the quality and efficiency of their services. Two other specific legislative and regulatory programs have focused on HAI-related activities: the recently created patient safety organizations (PSOs) administered by AHRQ and the ongoing Healthy People initiative involving all HHS agencies.

The Action Plan Responded to Policy Mandates and Expectations

As a result, a number of mandates and expectations have accrued for the Action Plan. Some of these resulted from direct legislative mandates, and others occurred as part of the policy development process. Regardless of the mechanisms, these mandates have shaped the environment within which the Action Plan operates and created expectations about its performance that will influence how it is judged. Perhaps paramount among the expectations shared by stakeholders were the view that the Action Plan would attempt to reduce duplication of effort within HHS and across the Federal government and the belief that the Plan would include a strategy for coordination of HAI prevention efforts and resources across government at the Federal, state, and local levels.

Input Evaluation Results

To gather expert input on the plan, the Deputy Secretary of HHS tasked the Office of Public Health and Science (OPHS) to convene an interagency Steering Committee to develop and implement the Action Plan. The Steering Committee was formed in the summer of 2008. Composed of senior-level representatives from HHS Offices and Operating Divisions, the Steering Committee was chaired by Donald Wright, MD, MPH, Deputy Assistant Secretary for Healthcare Quality, and staffed by the Office of Healthcare Quality (OHQ), within the HHS Office of Public Health and Science (OPHS). The Steering Committee brought together prominent clinicians, scientists and other public health professionals from across HHS agencies to develop the Action Plan, including the Agency for Healthcare Research and Quality (AHRQ), the Office of the Assistant Secretary for Public Affairs (ASPA), the Office of the Assistant Secretary for Planning and Evaluation (ASPE), the Centers for Disease Control and Prevention (CDC), the Centers for Medicare & Medicaid Services (CMS), the Food and Drug Administration (FDA), the National Institutes of Health (NIH), the Office of the National Coordinator for Health Information Technology (ONC), and OPHS. Moreover, these organizations took on critical responsibilities related to specific working groups that report to the HHS Steering Committee and are tasked with establishing objectives and tracking the progress of activities in order to achieve the Action Plan's goals.

As with the context evaluation, the input evaluation provided both descriptive and judgmental assessment. Criteria include concordance with stated goals, comparisons with other programs and with the scientific literature. Our input evaluation identified a number of perceived strengths and weaknesses in the Plan's design and initial implementation. Some of these were related to leadership and strategy, centering on how to ensure coordination and use available information to guide decision-making and accountability among stakeholders; others related to knowledge development, advancing research and strengthening the evidence base on HAIs. Knowledge development is particularly important in the selection of infections in the Action Plan, as well as in improving perceived limitations of the Action Plan related to the setting of HAI prevention targets, given that many of the key stakeholder groups in HAI prevention, such as physicians and other healthcare professionals, have high expectations for quality and safety initiatives to be evidence-based. The Action Plan was also seen as spurring initial infrastructure development and accountability around the plan and strengthening networks and relationships for action. Finally, inputs to the Action Plan were perceived as having improved the basis for adoption of HAI prevention practices through the selected set of priority infections. At the same time, deficiencies were identified in terms of inputs to the Action Plan related to its operational specifications and the derivation of metrics for HAI prevention targets. Both of these were considered, by the institutions and professionals providing health care at the local level, to hinder adoption of HAI prevention practices.

Implications for Ongoing Implementation of the Action Plan

Based on our findings from the Context, Input, and Baseline Data Inventory evaluations, we identified opportunities and challenges for next phases of the Action Plan implementation. These are organized into three clusters: data/IT systems, research, and implementation.

(1) Data/IT systems present an opportunity to detect patterns and trends rapidly as well as support public transparency for HAI rates. However, data/IT systems are currently challenged by the quality and validity of existing HAI surveillance data, inadequate standardization of clinical definitions for HAI conditions and metrics for measuring HAI prevention processes and rates, limited interoperability among data collection and reporting systems (e.g., between clinical reporting and administrative data surveillance systems, or between surveillance and public or payer reporting systems), limited scope of HAI prevention practices or conditions monitored, and the burden of current reporting systems requiring separate manual entry of data by busy and already overtaxed clinical professionals.

(2) Research presents the opportunity of organizing and identifying the gaps in knowledge and practice related to basic laboratory science, epidemiology, and prevention practice, but challenges remain in prioritizing what should be studied, identifying the available evidence, determining the standards for evidence-based practices, and deciding how research findings can be applied to improve quality of care at the bedside, to name just a few.

(3) Implementation of strategies and activities recommended by the Action Plan presents the opportunity to prioritize existing recommendations for infection control and clinical practices to enhance prevention; however, a major challenge resides in how to ensure the adoption of effective prevention practices.

To address these needs, the IMPAQ/RAND team outlined three strategies for the HHS Steering Committee and working groups to consider as the Action Plan evolves: increasing the engagement of stakeholders both within and external to the Federal government; acknowledging prevalent conceptual and implementation tensions between differing major perspectives on HAIs; and creating a supplementary document to outline the steps necessary to achieve each Action Plan goal.

Recommendations

Based on our findings from this phase of the evaluation, the IMPAQ/RAND team made a series of recommendations to the Office of Healthcare Quality and Steering Committee of the HHS Action Plan on key strategic and implementation issues. **Exhibit S.1** summarizes the findings and recommendations for each of these issues.

Exhibit S.1

Issue	Findings	Recommendations
Resource duration and predictability	While the Action Plan has attracted substantial public policy and funding support, the lack of predictability and sustainability of funds leads to inefficiencies with available resources and lack of deliberate consideration of the advantages and disadvantages of various alternative strategies for implementing HAI processes.	Aim for a baseline sustainable budget to support core activities that will be in place for at least several years and allow various projects to be considered and implemented as budgets expand and contract. The predictability of this approach can support more effective input strategies.
Engaging relevant Federal agencies	Although HHS promptly engaged almost all the relevant Federal agencies, there were two exceptions—the National Institute of Allergy and Infectious Diseases (NIAID) and the military health services within the Department of Defense.	Make explicit efforts to engage NIAID and the Department of Defense and integrate their expertise and assets into the Action Plan.
Encouraging coordination among Action Plan agencies	While the goals of the Action Plan emphasize well-coordinated interactions, and while structures have been established to enhance communication and coordination, the specific interactions among organizations, policies, and stakeholders required to support Action Plan goals are just emerging. Meanwhile, the need for additional insights into networks and relationships among key agencies and stakeholders will increase as the pace of implementation quickens.	Develop an inventory of organizational goals, projects, and programs associated with the Action Plan as a supplement to the HAI Baseline Data Inventory developed during the first-year evaluation of the Action Plan.
Engaging and leveraging external stakeholders	Despite extensive solicitation and documentation of stakeholder input, external stakeholders generally lack awareness of the scope of plan activities and how their efforts fit into the larger initiative; and a few perceive that their concerns have not been fully addressed. There are also several additional stakeholder groups with potential contributions to the Action Plan that have yet to be adequately engaged.	Reiterate the value of external stakeholders as partners to the Action Plan. Close the loop with stakeholder groups that provide input, to ensure understanding of how specific concerns have been addressed. Specify the explicit roles that different stakeholder groups may play in implementation of each element of the Action Plan. Conduct explicit outreach to the additional stakeholder groups identified, where resources permit.
Incorporating differing stakeholder perspectives and interests	The Action Plan's stated goals and targets were useful and generally well supported by stakeholders. However, underlying tensions among stakeholder groups related to differences in perspectives and interests may hinder progress of the Action Plan as the number and pace of activities increase.	Devote more attention to understanding tensions between various perspectives and interests related to HAI prevention, followed by efforts to build solutions that address underlying tensions.
Coordinating	HHS has described and disseminated	Move forward with the development of

Issue	Findings	Recommendations
the breadth of programs and projects that constitute the Action Plan	information about funded programs and projects, but a systematic inventory is only beginning to be compiled.	the Project and Program Inventory of Action Plan-related activities. As the inventory emerges, a more complete picture of the strengths and weaknesses of various individual programs and projects should be recognizable. This may prompt new efforts to fill strategic gaps, reduce redundancies, or ensure complementarities in Action Plan activities.
Strategically assessing the value of potential new programs	The Evaluation Working Group and this evaluation team should be working towards a more consistent approach to identifying criteria for comparing the effectiveness of potential programs within and across agencies. Underlying tensions, such as the relative value of short- and long-term goals associated with basic and clinical research—as compared with community engaged and implementation research—should be considered.	Move forward with the development of a Conceptual Model of the Action Plan, the Project and Program Inventory, and the Data Inventory. Use these as substrates to identify criteria for comparing potential programs within and across program areas

Concluding Observation

The HHS Action Plan to Prevent Healthcare-Associated Infections is a large-scale, continuous initiative designed to be continually evolving and adaptive. Our use of the CIPP evaluation model is structured so that the findings included in this report from the first year’s Context and Input evaluations provide formative strategic feedback to the initiative at this stage as well as the foundation for the subsequent Process and Product evaluations. These evaluations will focus on documenting and analyzing the implementation process and key outcomes of the Action Plan as it moves into its second year of existence and beyond. Central tasks of those evaluations will include characterizing and tracking the range of various activities subsumed under the Action Plan, understanding how those efforts have responded to opportunities to leverage other thriving movements within healthcare improvement (such as patient safety, implementation science, and “meaningful use” of health information technology), and establishing baseline measures of HAI rates and prevention practice adoption.

1. OVERVIEW OF THE LONGITUDINAL PROGRAM EVALUATION

1.1 Background

The National Evaluation of the Department of Health and Human Services' (HHS) Action Plan to Prevent Healthcare-Associated Infections is a large-scale formative evaluation project, designed to generate strategic insights across stakeholders. Conducted by IMPAQ International and the RAND Corporation (the IMPAQ/RAND team), the evaluation seeks to:

1. Record the content and scope of the Action Plan to Prevent Healthcare-Associated Infections (hereafter, "Action Plan"); its current design, recorded progress, and what it can add in the future;
2. Establish baseline data and provide feedback on how to strengthen ongoing assessments of the scope of healthcare-associated infections (HAIs) and interventions, how to reduce HAIs, and how to begin to understand the effectiveness of those interventions; and
3. Provide strategic insights from ongoing processes and outcomes regarding opportunities to reduce HAIs.

The widespread prevalence and enormous cost of HAIs have been recognized as public and personal-level health problems.² HAIs, particularly those developed during hospitalization, represent a major patient safety concern. An estimated 1.7 million HAIs are diagnosed annually in hospitals and associated with approximately 100,000 deaths.^{3,4} As mechanisms to identify and monitor HAIs have become more sophisticated, opportunities for reducing their incidence and adverse effects have evolved. Multiple strategies can be employed to reduce HAIs, particularly those infections that are most prevalent.³⁻⁵ These HAIs include central line-associated blood stream infections (BSIs), ventilator-associated pneumonia (VAP), catheter-associated urinary tract infections (CAUTIs), and surgical site infections (SSIs), as well as infections associated with *Clostridium difficile* and methicillin-resistant *Staphylococcus aureus* (MRSA). In most instances, health care professionals cannot link any particular medical error with HAIs; however, using evidence-based preventive measures reduces HAIs across multiple health care settings.³⁻⁵

Substantial opportunities exist for adopting evidence-based processes and for reducing rates of HAIs. For example, reductions in using devices (e.g., urinary catheters) known to be associated with urinary tract infections, and improved techniques (e.g., hand washing and bundling services) for using devices (e.g., central indwelling venous catheters) have led to marked improvements in infection-associated morbidity, mortality, and costs.³⁻⁵

To address the national epidemic of HAIs, HHS developed the Action Plan and initially implemented it in 2009 as a systematic effort to reduce HAIs and associated morbidity, mortality, and costs.⁶ Several agencies within HHS are implementing the Action Plan, with substantial national, regional, statewide, and local visibility. In its current form, the Action Plan represents the first step in an evolving program. A number of HHS agencies already have

projects and activities underway to implement the Action Plan. Agencies will add other projects as Action Plan activities proceed.

IMPAQ International and RAND Corporation received a contract in 2009 to conduct an independent, outside evaluation of the department's HAI prevention efforts, guided and driven by the Action Plan. To meet the objectives of the national evaluation of the HHS Action Plan, the IMPAQ/RAND team is studying four key factors:

1. The **context** in which the Action Plan began;
2. The **inputs** considered and initiated to allow the Action Plan to develop;
3. The **processes** associated with implementing Action Plan-related efforts; and
4. The **products** and outcomes of these activities.

Overall, the IMPAQ/RAND evaluation will consider all current program activities and other activities initiated during the course of the evaluation although we anticipate the addition of future projects after completion of the proposed evaluation. The evaluation generates information about early progress in achieving the Action Plan goals. Participating agencies can use this information when deciding about future projects to address identified issues and reinforce progress toward selected goals.

This evaluation report describes the activities the IMPAQ/RAND team conducted during Year 1 of the national program evaluation. These efforts concentrated on understanding the context and inputs in the Action Plan's development and launch. We identified important contextual drivers and inputs through an extensive review of key documents that led up to and resulted from the development and implementation of the Action Plan and through interviews with key stakeholders.

Below, we summarize our efforts and findings from the Year 1 evaluation. Prior to describing the data we collected and our results, we provide a detailed description of the Context-Input-Process-Product (CIPP) model that guided our program evaluation efforts.⁷⁻⁹ CIPP is a well-established framework for conducting large-scale formative program evaluations. For example, RAND used the CIPP model to evaluate the AHRQ multi-year Patient Safety Initiative.¹⁰ As described, this Year 1 report focuses on our context and input analyses and results. Future reports will describe our evaluation of the processes associated with the Action Plan and the resulting products, Year 2 and Year 3 reports respectively.

1.2 The CIPP Evaluation Model

The IMPAQ/RAND team applied the CIPP Model to the Action Plan as a means to provide a comprehensive approach to the evaluation.⁷⁻⁹ As an evaluation tool, the CIPP Model facilitates making judgments about whether aspects of the program being evaluated are adequate or not. Standard approaches to the CIPP Model range from predominantly descriptive methods to more evaluative methods. Within this Year 1 report, much of the CIPP model evaluation is

descriptive focusing on how the Action Plan came to be. Where Year 1 has provided adequate information to permit a meaningful judgment, this has been implemented focusing primarily on two criteria. The first implicit criterion asks whether the totals are consistent with policymaker and stakeholder intent. The second criterion asks whether the program outlines a set of activity choices to provide a sound set of stepping stones for the development of processes and products (outcomes). The Year 1 Report supplements description of whether the program's goals are reasonable, with what should be done, what needs are worth addressing through programs, and what resources should be marshaled to address those needs. Future reports in subsequent years will include additional criteria as data become available to the Evaluation Team. For example, it is anticipated that as more data are accumulated, the Action Plan's approach will be compared with (benchmarked to) that of other programs. Where possible, the mechanisms and theories of action of the HHS HAI Action Plan will be compared against findings from the scientific community. The evaluation focuses on the aggregate effect of components of the Action Plan, recognizing that many of the components are evolving in response to a changing set of challenges. The Model's support for a comprehensive evaluation of components and the aggregate program also serves to facilitate comparability across evaluations within and across agencies.

CIPP is a well-accepted strategy for improving systems that encompass the full spectrum of factors involved in operating a program.⁷⁻⁹ The following definitions describe the four core model components represented in the CIPP acronym.¹⁰

- **Context Evaluation** – assesses the circumstances stimulating creation or operation of a program as a basis for defining goals and priorities and for judging the significance of the outcomes.
- **Input Evaluation** – examines alternatives for goals and approaches for either guiding choice of a strategy or assessing an existing strategy against the alternatives. This can include concordance with policy makers or other stakeholders, benchmarking a program against competitors or assessing whether the selected strategies individually or in aggregate, and in sequence, are likely to support the process evaluation and expected relationships between processes and products (outcomes).
- **Process Evaluation** – assesses progress in implementing plans relative to the stated goals for future activities and outcomes. The process evaluation documents projects and activities to implement the program and assesses progress in implementing them, including identifying factors observed affecting such progress.
- **Product Evaluation** – identifies the various and collective effects of the overall program and individual projects, including consequences for various stakeholders, intended or otherwise, to determine its effectiveness and provide information for future program modifications.

The CIPP Model offers a comprehensive approach to evaluation that uses a systematic path to delineating, obtaining, and providing useful information for judging ongoing relationships between activities and decisions. The model posits an ongoing cycle of activities influencing decisions that influence selection and implementation of subsequent activities, which in turn

influence future decisions and more activities. CIPP conceptualizes evaluation as a systematic and continuing set of activities that supports decision-making and accountability. Properly using CIPP requires understanding decision-making and procedures for transitioning decisions to services, services to subsequent decisions, and so on.

1.3 Using the CIPP Evaluation Model to Support Decision-Making

In addition to its qualities for supporting large-scale, dynamic projects, the CIPP model can contribute to program decision-making. This facet is central to this evaluation's formative nature, helping the IMPAQ/RAND team provide analyses that can support decision-making for key stakeholders. To achieve this purpose, CIPP emphasizes identifying information that is useful for judging ongoing relationships between activities and decisions and those procedures involved with transitions between activities, decisions, services, and subsequent decisions. CIPP posits an ongoing cycle of activities that influence decisions, which in turn influence selection and implementation of subsequent activities and services. Again and again, these activities (actions and services) influence future decisions and subsequent activities and decisions.

As we use CIPP to characterize the Action Plan, we must understand the activities and decision-making relevant to the plan. We can characterize each of the four CIPP components according to decisions that can be made, obtaining appropriate data, and sharing analyses of the data with the decision-makers. In that way, our independent longitudinal analysis provides ongoing formative inputs, rather than reserving input for the end stages of the Action Plan or after the fact.

Exhibit 1 shows the relationships among the four components of the CIPP model (Context, Inputs, Process, and Product), the four kinds of decisions relevant to evaluation, the information to be gathered during the evaluation to inform decision-making, and the way in which the information will be used to guide a formative evaluation and related improvements in decision-making.

The Context and Input evaluations constitute the main foci of the Year 1 work. This work included developing a sampling plan, conducting stakeholder interviews, and undertaking literature and document reviews. The Context and Input evaluations serve as a historical record of the Action Plan's creation—its introductory context and the challenges it faced. The Context evaluation record reveals the decisions considered for developing the Action Plan's goals. The Input evaluation reveals alternative strategies considered regarding how the Action Plan program's structure could help accomplish the goals. The Context and Input evaluations also serve to inform the forthcoming Process and Product components.

Exhibit 1: Relationships between CIPP and Decision-Making

CIPP Evaluation Components	Operations to Support Components of the CIPP Model	Target Information to Inform Evaluation Component	How Information Guides Formative Evaluation and Improves Decision-Making
Context Evaluation	<i>Planning</i> to identify what should be done	<i>What should the program do?</i> Strengths and weaknesses of the system to inform what the program under evaluation should accomplish.	Plan improvement-oriented objectives across all system levels.
Input Evaluation	<i>Structuring</i> to inform how the program effort should be done	<i>How should the program accomplish its goals?</i> Strengths and weaknesses of alternative strategies to inform how program effort should be conducted.	Select specified objectives to be supported.
Process Evaluation	<i>Implementing</i> to identify whether the program is being carried out correctly	<i>Is the program being implemented correctly?</i> Strengths and weaknesses of implementation strategies to inform whether the program is being performed correctly.	Strengthen strategy and/or implementation.
Product Evaluation	<i>Assessing</i> to identify whether the program is working	<i>Is the program working?</i> The extent to which program objectives are being met to inform whether interventions should be changed.	Change the procedures employed to achieve objectives by continuing, modifying, or terminating them.

Adapted from Stufflebeam.^{8,9}

In the Process evaluation, we will consider the strengths and weaknesses of strategies selected for implementation. This evaluation can reveal program performance that is consistent with the project goals and also disclose how program implementation can improve. Additionally, the Process evaluation documents programs and projects so successes can be replicated, while less successful programs can benefit from opportunities for improvement.

Finally, in the Product evaluation, all of the prior components of the CIPP model will be reconsidered and updated to support a synthetic understanding of the extent to which program objectives have been met. Where possible, specific recommendations for changing interventions to better support program objectives can be identified and implemented, thereby restarting the CIPP cycle and its support of iterative decision-making.

1.4 The CIPP System Framework for the HAI Prevention Program

The CIPP evaluation model is most valuable when each component is viewed in relation to the others. The proposed evaluation approach uses a model, similar to that developed in RAND's evaluation of AHRQ's Patient Safety Initiative, to "tell the story" of the Action Plan "in a way

that is intuitively accessible to HHS and other government and nongovernment staff, policymakers, and stakeholders, who will be using the evaluation results.”¹⁰ In this section, we present our framework, which is specifically refined for the structure and scope of the Action Plan evaluation. This framework is intended to help:

- Track a changing mix of activities over time and assess their individual contributions to the overall Action Plan;
- Map each CIPP evaluation component directly to individual stages of the Action Plan initiative, to ensure that the evaluation addresses the entire Action Plan program;
- Summarize the overall effects of the program as a function of the collective contributions of its multiple activities;
- Examine the roles and responsibilities of multiple organizations engaged in the program at Federal, State, and community levels; and assess their contributions to preventing incidence of HAI in the country; and
- Examine the effects of the program including impact on HAI rates as well as other relevant outcomes and consequences.

The system framework guiding the evaluation, shown in **Exhibit 2**, consists of three tiers of elements. The first tier is Leadership and Strategy, which represents the HHS leadership role in the Federal program, and includes both the work of the HHS Steering Committee leading the HAI initiative and the Action Plan itself as a strategy document. This element will be the subject of the *Context* and *Input* evaluations.

The second tier contains four elements—HAI Data and Monitoring, Knowledge Development, Infrastructure Development, and HAI Prevention Practice Adoption. These elements represent the spectrum of implementation activities that are, or will be, undertaken in the program, at the Federal, State, and community level and will involve multiple organizations and stakeholders. The existing conditions in the health care field and the Action Plan strategies related to these elements will also be the subject of the *Context* and *Input* evaluations, while their implementation will be the subject of the *Process* evaluation.

The *third* tier is effects on stakeholders, which includes not only effects on HAI rates, but also a range of other effects on various program stakeholders. This element will be the subject of the *Product* evaluation.

Exhibit 2: System Framework for the HAI Prevention Program

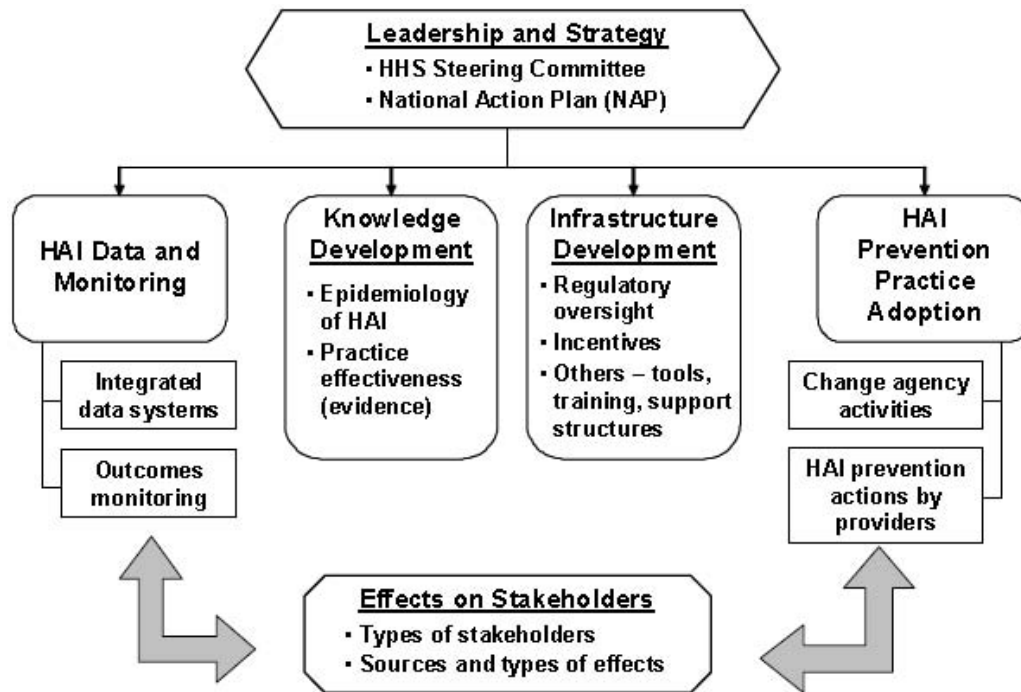


Exhibit 3 presents the planned schedule for performing specific tasks under the four CIPP evaluation components. Year 1 has focused on the development of the conceptual model and the details of using the CIPP Model. During Year 1, we conducted the Context and Input evaluations and began planning and preparatory work for the Process and Product evaluations, including an inventory of HHS data systems for HAI, which is published as a separate report.¹¹ During Years 2 and 3, the focus of the evaluation will be on the Process and Product evaluations, which will also be structured according to the framework provided by the CIPP model and the system framework shown in Exhibit 2.

**Exhibit 3: Schedule for Performing the CIPP Inspired Evaluation for the Action Plan Program,
by Year**

Evaluation Task by CIPP Component	Year 1	Year 2	Year 3
Context Evaluation			
Document and assess contextual factors	X		
Document Congressional and legislative intent for the initiative, and funding	X		
Assess mandates and requirements for HHS	X		
Characterize effects of contextual factors and mandates on HHS strategy	X		
Input Evaluation			
Assess HAI program goals and objectives	X		
Examine strategies selected and alternatives	X		
Identify stakeholders involved or affected by program	X		
Process Evaluation			
Prepare process measures plan	X		
Characterize HAI projects and code for descriptive summary of their activities	X	X	
Assign each HAI project to system element(s) in the evaluation framework	X		
Gather data on process measures		X	X
Examine collaborations in State-level projects		X	X
Gather data on implementation progress		X	X
Coordinate with ARRA evaluation and HAC POA evaluation (not projects for this evaluation)	X	X	X
Product Evaluation			
Conduct inventory of HHS data systems for HAI	X		
Prepare baseline assessment for adoption and effect measures using existing data in inventoried systems		X	
Prepare adoption plan		X	
Assess collective effects of HAI projects on HAI rates, stakeholders, costs, cost-effectiveness, usability			X
Assess adoption by non-HAI projects (diffusion)			X

1.5 Organization of This Report

In this report, we present a brief overview of the Action Plan in Chapter 2 and a review of the evaluation methods we employed for the Context and Input evaluations in Chapter 3. We then present the Context evaluation results in Chapter 4 and the Input evaluation results in Chapter 5. We conclude with two implications chapters. Chapter 6, explores the implications of these evaluation findings for ongoing implementation of the Action Plan. Chapter 7 explores what the current findings imply for the subsequent phases of the evaluation—the planned Product and Process evaluations. While this Year 1 report highlights the descriptive components of the CIPP Model approach, some evaluative criteria are also described. It is anticipated that the forthcoming annual reports will increasingly supplement descriptive approaches with more evaluative criteria.

2. THE HHS ACTION PLAN TO PREVENT HEALTHCARE-ASSOCIATED INFECTIONS

In this chapter, we provide an overview of the Action Plan and its components and objectives.

2.1 Healthcare-Associated Infections and the HHS Action Plan

In 2008, the GAO released a report that was critical of HHS leadership on the issue of HAI and of the coordination regarding HAI issues across operating divisions within HHS. This report was followed by Congressional hearings on the subject. The HHS Steering Committee for the Prevention of Healthcare-Associated Infections was subsequently established and charged with developing a comprehensive strategy to prevent and reduce HAIs. As a result of this mandate, in June 2009 HHS issued a plan titled Action Plan to Reduce Healthcare-Associated Infections, which established national goals for HAI prevention, including key actions for achieving short- and long-term objectives.

The Action Plan is intended to enhance collaboration across HHS operating divisions as well as with external stakeholders in order to strengthen the coordination and impact of national efforts. The Office of Healthcare Quality (OHQ) coordinates the HHS Steering Committee responsible for implementation of the Action Plan. OHQ is located within the Office of the Assistant Secretary for Health, under the Office of the Secretary in the U.S. Department of Health and Human Services.

The Action Plan describes the critical issues associated with HAIs, specifies strategies to address them, and identifies targets for reducing HAIs over the next 5 years. The Action Plan is organized into sections covering metrics and targets, research, information systems and technology, incentives and oversight, outreach and messaging, and coordination and evaluation. These areas were developed and guided by five working groups with leadership from appropriate HHS offices and agencies. The plan is designed to be a living document—that is, it will evolve as the working groups and the HHS Steering Committee launch projects and gain insights into the success of various initiatives.

2.2 Federal Agencies Participating In the Action Plan

Nine HHS operating divisions signed the Action Plan when it was released in June 2009. Four lead agencies took responsibility for drafting major sections of the initial Action Plan document: the Agency for Healthcare Research and Quality (AHRQ), the Centers for Disease Control and Prevention (CDC),¹¹ the Centers for Medicare & Medicaid Services (CMS), and the Office of Public Health and Science (OPHS).

The five other signatory agencies included the Office of the Assistant Secretary for Public Affairs (ASPA), the Office of the Assistant Secretary for Planning and Evaluation (ASPE), the Food and Drug Administration (FDA), the National Institutes of Health (NIH), and the Office of the National Coordinator for Health Information Technology (ONC). Two additional HHS agencies—

the Health Resources and Services Administration (HRSA) and the Indian Health Service (IHS)—also helped develop the plan and served on the Steering Committee and various working groups. Since the release of the Action Plan, the Veterans Health Administration (VHA) has joined the Steering Committee and working groups and represents the only non-HHS agency directly participating in the plan.

These agencies were enlisted to contribute specific expertise, resources, and capacity for developing and implementing the plan. (See Chapter 5 for further description of the roles taken by each agency to date.)

Personnel from these federal agencies, as well as other prominent clinicians, scientists, and other public health professionals within HHS, in concert with key individuals from other Federal departments, worked to develop a roadmap for addressing the important public health and patient safety issues presented by of HAIs in the short- and long-term.

2.3 Overview of the Action Plan

Representatives from these groups met during the first year to deliberate on current knowledge, research needs, and ways to prevent HAIs.

2.3.1 Five-Point Strategy to Support the HHS Action Plan Goals

The Action Plan included goals that set specific targets for reducing HAIs (detailed further below) toward which the health care and public health communities could move over the next five years. A five-point draft strategy to support these goals was released in the Executive Summary of the Action Plan. The plan identified five strategies for moving forward.

- Establishing an HHS Steering Committee for the Prevention of Healthcare-Associated Infections to oversee and further develop the Action Plan.
- Beginning to prioritize, in partnership with the HHS Secretary's Healthcare Infection Control Practices Advisory Committee (HICPAC), the scientific questions that need to be addressed to move the field forward and the current 1,200 recommended clinical practices to facilitate rapid implementation among healthcare organizations
- Identifying and exploring policy options for regulatory oversight of recommended practices and providing critical compliance assistance to select hospitals
- Working to establish greater consistency and compatibility of HAI data through developing standardized definitions and measures for HAIs.
- Striving to build on the principles of transparency and consumer choice to create incentives and motivate healthcare organizations and providers to provide better, more efficient care.

Exhibit 4 shows how these strategies map to the four process domains outlined earlier in the CIPP system framework indicating that these strategies cover each of the main functional areas within the healthcare system related to HAI prevention.

Exhibit 4: Characterizing the Five-point Draft Strategy of the Action Plan According to the Four Domains of Process as Outlined in CIPP-Inspired Evaluation Model

Five-Point Draft Strategies (as they relate to the four domains of process in CIPP Model)				
	HAI Data and Monitoring	Knowledge Development	Infrastructure Development	Adoption of HAI Prevention Practices
1. Establishing an HHS Steering Committee for the Prevention of Healthcare-Associated Infections to develop an Action Plan.			X	
2. Beginning to prioritize, in partnership with the HHS Secretary's Healthcare Infection Control Practices Advisory Committee (HICPAC), the scientific questions that need to be addressed to move the field forward and the current 1,200 recommended clinical practices to facilitate rapid implementation among healthcare organizations.		X		
3. Identifying and exploring policy options for regulatory oversight of recommended practices and providing critical compliance assistance to select hospitals.		X		
4. Working to establish greater consistency and compatibility of HAI data through developing standardized definitions and measures for HAIs.	X			
5. Striving to build on the principles of transparency and consumer choice to create incentives and motivate healthcare organizations and providers to provide better, more efficient care.		X		X

2.3.2 Five Early Activities under the HHS Action Plan

The HHS Steering Committee and its subgroups identified and undertook five specific activities during the development of the initial Action Plan document. **Exhibit 5** shows how these five early activities can be evaluated according to the four domains of process outlined in the CIPP model. This table shows that early activities have mostly addressed HAI Data and Monitoring and Knowledge Development (i.e., research-related) issues and have yet to fully address Infrastructure Development and Adoption of HAI Prevention Practices.

Exhibit 5: Characterizing the Five Early Activities Identified by the Action Plan

Five Early Activities by Four Domains of Process (as they related to the CIPP Model)				
	HAI Data and Monitoring	Knowledge Development	Infrastructure Development	Adoption of HAI Prevention Practices
Identification of metrics with corresponding national 5-year prevention targets	X			
Identification of gaps in the current knowledge of HAIs with the creation of an agenda for current and future research on HAIs		X		
Recommendations of the standardization of data elements and adoption and use of data and technology standards to track HAIs		X		
Documentation of the current regulatory and administrative authority and initiatives/strategies of CMS (working with other HHS Operating Divisions and Federal partners) used to prevent and combat HAIs		X		
Development of a progressive campaign to release and publicize the Action Plan in concert with a number of national partners in the Federal, academic, non-profit, and private sectors. This messaging and communications strategy will target a number of audiences using the principles of social marketing and risk communication to also reach the public at large.		X		

2.3.3 Ten Messages of the HHS Action Plan

Ten messages were developed for the Action Plan to communicate to various stakeholders and the public, including health care organizations, professional provider organizations, governmental agencies, non-profit public health organizations, and public audiences. Like the early strategies and activities, each message can be characterized according to the four domains of process as outlined in the CIPP model (**Exhibit 6**). These ten messages span the CIPP process themes, illustrating the far reach of even the initial broad messages of the Action Plan.

Exhibit 6: Characterizing the Top Ten Messages of the Action Plan According to Four Domains of Process as Outlined in CIPP Model

Top Ten Messages by Four Domains of Process as Outlined in CIPP Model				
	HAI Data and Monitoring	Knowledge Development	Infrastructure Development	Adoption of HAI Prevention Practices
Many healthcare-associated infections are preventable.		X		
A systemic approach to reducing the transmission of disease can be more effective than disease-specific approaches.		X	X	X
Developing and supporting basic and translational studies to address the gaps in the science in this field will allow generation of additional strategies to reduce the risks of HAI transmission.		X		
It will take a strong partnership between Federal and local/state governments and communities to truly help prevent HAIs. HHS is committed to this partnership and many of its Operating Divisions are and will be involved.				X
Best practice education for providers and other healthcare personnel is critical to prevention.		X	X	X
Specific metrics and national targets have been developed by HHS in concert with national experts on controlling infections.	X			
Educating patients on HAIs and how to prevent them is a critical part of the national effort.		X		
An informed media can help promote the education of the American public about the need to prevent HAIs and what HHS and its partners are doing.		X		
Preventive steps to control and prevent HAIs are cost-effective, save lives, and reduce disability for Americans.		X		
HHS and its partners are working closely with providers, health systems, community leaders, and governments to prevent HAIs.			X	X

2.4 Specific Goals and Recommendations of the Action Plan

The chief goals of the Action Plan consist of a set of targets to reduce HAI rates for six healthcare-associated infections or specific causative organisms:

- surgical site infections (SSIs),
- central line-associated bloodstream infections (CLABSIs)
- ventilator-associated pneumonia (VAP)
- catheter-associated urinary tract infections (CAUTIs)
- *Clostridium difficile* (*C. difficile*)
- methicillin-resistant *Staphylococcus aureus* (MRSA)

This list of initial HAI conditions and related targets was developed by the Prevention and Implementation Working Group. In addition, different chapters of the Action Plan specified priority recommendations to support these targets developed by the Research, Information Systems and Technology, Incentives and Oversight, and Outreach and Messaging Working Groups, as summarized below.

2.4.1 Priority Recommendations of the Prevention and Implementation Working Group

The Prevention and Implementation Group made an explicit set of priority recommendations. Other goals and recommendations were also stated. Throughout our evaluation, we will consider the processes aimed at both these priority recommendations, as well as processes aimed at other goals and recommendations in the Prevention and Implementation chapter of the Action Plan. As documented in the Action Plan, the priority recommendations of this working group are to:

- Progress towards 5-year national prevention targets;
- Use and improve the metrics and supporting systems needed to assess progress towards meeting the targets; and
- Consider recommendations, grouped by priority module, outlined for each of the guidelines addressed.

The Prevention and Implementation Working Group prioritized six HAIs on which to focus national prevention efforts. The first four categories of infection account for approximately three-quarters of HAIs in the acute care hospital setting: SSIs, CLABSIs, VAP, and CAUTIs. The other two categories reflect concerns about specific organisms that cause HAIs—*Clostridium difficile* (*C. difficile*) and MRSA. The Prevention and Implementation Working Group initially recommended seven metrics and National 5-Year Prevention Targets, as outlined in **Exhibit 7**.

Exhibit 7: Metrics and National 5-year Prevention Targets

Metric Number and Label	Metric	Measurement System	National 5-Year Prevention Target
1. CLABSI 1	CLABSIs per 1000 device days by ICU and other locations	CDC NHSN; Administrative discharge data	CLABSIs per 1,000 device days by ICU and other locations below present NHSN 25th percentile by location type (75% reduction in Stratified Infection Ratio)
2. CLABSI 4	Central line bundle compliance (non-emergent insertions)	NHSN CLIP module	100% compliance with central line bundle (non-emergent insertions)
3. C diff 1	Case rate per patient days; administrative/discharge data for ICD-9 CM coded <i>Clostridium difficile</i> Infections	Administrative discharge data; NHSN MDRO module	30% reduction in the case rate per patient days and administrative/discharge data for ICD-9-CM coded <i>Clostridium difficile</i> Infections NOTE: Preventability of endemic CDI is unknown; therefore, the meeting attendee experts suggested that HHS revisit this target in 2 years as prevention research findings may become available
5. MRSA 1	Incidence rate (number per 100,000 persons) of invasive MRSA infections	CDC EIP/ABCs	50% reduction in incidence rate of all healthcare-associated invasive MRSA infections
6. SSI 1	Deep incision and organ space infection rates using NHSN definitions (SCIP procedures)	CDC NHSN	Median deep incision and organ space infection rate for each procedure/risk group will be at or below the current NHSN 25th percentile
7. SSI 2	Adherence to SCIP/NQF infection process measures (perioperative antibiotics, hair removal, postoperative glucose control, normothermia)	CMS SCIP	95% adherence rates to each SCIP/NQF infection process measure

These metrics pertain to five of the priority HAIs. Given the general lack of consensus on acceptable metrics for VAP, the selection of measurable targets for that category was omitted pending further review and refinement by experts. Note that the metrics identified were

further refined in Appendix G of the Action Plan, following consideration of stakeholder feedback. The revisions included the following changes:

- Rather than using prevalence rates to track HAI prevention progress, the revised list applies the standardized infection ratio (SIR)¹ to many of the seven metrics listed in **Exhibit 1**. These include CLABSI 1, C diff 1 (based on NHSN), CAUTI 2 (based on NHSN), and SSI 1.
- CLABSI 4 was renamed “CLIP 1”; SSI 2 was renamed SCIP 1.
- C diff 1 was separated into 2 metrics: C diff 1 and C diff 2. In Appendix G, C diff 1 captures surveillance using administrative discharge data, while C diff 2 captures surveillance using NHSN.
- Surveillance of CAUTI 2 is specified in Appendix G as using only NHSN rather than NHSN and administrative discharge data.
- MRSA 2, which was included among the 17 candidate metrics listed in Appendix A, is included in Appendix G.

2.4.2 Priority Recommendations of the Research Working Group

The Research Working Group developed recommendations to address specific knowledge gaps in basic science, epidemiology, and practice. The focus of the basic science research should be to develop strategies for preventing and/or eliminating biofilms associated with medical devices. The epidemiology research should:

- Study the epidemiology of bloodstream infections that occur outside of the hospital;
- Establish the preventability of CDI through a regional hospital collaborative intervention;
- Establish the preventability of unnecessary antimicrobial use through a multi-center collaborative intervention; and
- Establish the preventability of SSI through a multi-center collaborative intervention.
- Finally, the focus of the practice research should be to assess the effectiveness of the ICU-wide application of a MRSA decolonization strategy.

¹ The SIR is equal to the ratio of observed infections to expected infections. Thus, an SIR greater than 1 indicates that there were more observed infections than were expected, while an SIR less than 1 indicates that observed infections were fewer than expected. The denominator (expected infections) is based on a reference period and geography. For example, the State-specific NHSN report bases expectations on national CLABSIs over the period January 2006–December 2008. The SIR is useful in combining several HAI rates that are stratified for risk adjustment purposes (e.g., by care setting, in the case of NHSN CLABSI data) into a single, easily interpreted number.

An additional set of recommendations was to conduct research to enhance the implementation and impact of existing, evidence-based infection control practices:

- Investigate the human cultural and organizational barriers to successful implementation of practices at the unit and institutional levels;
- Develop and evaluate novel and automatable strategies for measuring HAIs;
- Evaluate and validate standardized post-discharge surveillance methodology;
- Develop proxy measures for VAP (i.e., acute lung injury) for inter-facility comparisons; and
- Develop standardized methods for measuring and reporting compliance with broad-based prevention practices (e.g., hand hygiene).

2.4.3 Priority Recommendations of the Information Systems and Technology Working Group

This working group emphasized four recommendations:

- Form an Interagency Working Group to enhance the Federal capacity to lead a national prevention strategy;
- Conduct a comprehensive HAI database inventory to guide future plans for near-, mid-, and long-term integration and interoperability projects and to establish the extent of definitional alignment and data element standardization needed to link HAI data across the nation;
- Enhance individual agency systems to extend their coverage or establish new interfaces with other systems; and
- Accelerate transition to electronic reporting by health care facilities to reduce their reporting burden and increase timeliness, efficiency, comprehensiveness, and reliability of the data.

2.4.4 Priority Recommendations of the Incentives and Oversight Working Group

This working group emphasized the need to:

- Improve regulatory oversight of hospitals and improve CMS oversight of the hospital accreditation program by refining the current method of measuring Accreditation Organization performance, enhancing surveyor training and tools, and adding sources and uses of infection control data;
- Continue to incorporate measures of infection prevention and outcomes into Hospital Value-Based Purchasing (VBP) Plan methodology through implementing performance-based payment for hospitals, including measures of infection prevention and outcomes as a basis for payment; and

- Expand measures in CMS Hospital Compare which improves the quality and transparency of hospital care by increasing public accountability and provides consumers access to important hospital quality of care measures.

2.4.5 Priority Objectives of the Outreach and Messaging Work Group

The Outreach and Messaging Working Group prioritized the need to:

- Increase support for the Action Plan, and
- Increase knowledge and awareness of key messages and prevention practices among providers, consumers, the media, and general public.

3. METHODS FOR THE CONTEXT AND INPUT EVALUATIONS

This chapter describes the methods the IMPAQ/RAND team employed during the first year of the Action Plan evaluation. We conducted a document and literature review and interviews with key stakeholders to gain information about (1) the context in which the Action Plan was developed and (2) specific inputs to the Action Plan. The review provided factual information about context and inputs, while the informant interviews enriched these data by providing information about the perceptions and experiences of stakeholders involved with the development of the Action Plan. Many of these stakeholders will also be responsible for implementing the Action Plan and thus they were able to provide some initial insight into the Process component of the CIPP evaluation framework as well.

In the sections that follow, we first describe our approach to the document and literature review and then our approach to the key informant interviews. In the final section of this chapter, we briefly describe our work inventorying available databases for tracking and studying HAIs. This activity is contributing to our evaluation of the Action Plan as a document (specifically related to the Product phase), but is described in a separate, detailed report;¹¹ therefore, detailed information is not presented here. Our intent in discussing it in this chapter is to explain how this work fits within our systematic application of the CIPP model.

3.1 Document and Literature Review

The goal of the document and literature review was to identify documents that might inform the Context and Input evaluations. We included three types of documents: (1) documents that provided important historical context to understand catalysts for the Action Plan; (2) documents that played a direct role in the development of the Action Plan; and (3) documents produced as a result of Action Plan-related activities. This third set of documents will carry over to the Process evaluation component of this project.

3.1.1 Sampling Frame Development for the Document and Literature Reviews

In conducting the document review, we did not restrict ourselves to specific types of documents. We included journal articles, books, internal HHS documents, publicly available reports, meeting minutes, presentation slides from Action Plan-related meetings, individual Web site pages, and other relevant materials.

To identify specific documents and literature to include in the review, we drew upon the following sources: (1) literature cited in the Action Plan; (2) documents recommended and/or provided to the IMPAQ/RAND team by interviewees; (3) Steering Committee and working group meeting minutes; (4) supplemental literature that met our criteria for inclusion in the Document/Literature review; and (5) a systematic review of Action Plan agency Web sites for all Action Plan-related documents.

Supplemental literature includes additional documents and literature that could potentially be relevant to the Context and Input evaluations but was not identified through the methods in the first three categories above. Sources of the supplemental literature included organizational newsletters, which team members regularly subscribe to, tables of contents from journals that team members regularly read, and information shared by colleagues. To keep the document and literature review closely focused on Action Plan-related information, as well as to avoid having the scope of the task balloon beyond what the project resources would allow, we applied strict criteria to potentially relevant supplemental literature. The inclusion criteria specified that supplemental literature needed either to be a white paper or research paper produced by an HHS agency participating in the Action Plan and related to HAIs or provide policy context impacting HHS (e.g., statements by the HHS Secretary, HHS position statements, etc.) to be included.

To ensure that we had a complete sample of Action Plan-relevant documents, we conducted a systematic review of the Web sites associated with the four primary HHS agencies involved in the Action Plan – AHRQ, CDC, CMS, and OPHS. The purpose of reviewing the Web sites was to identify and retrieve relevant information sources to include in the document and literature review, as well as to characterize the type, amount, scope, and level of priority given to Action Plan-related information on the sites. This latter information was recorded in a standard abstraction form for each Web site (see Appendix A, HHS Agency Web Site Review). Documents relevant to the Context and Input evaluations were added to the sampling frame for the document and literature review and subjected to the same analysis methods (described below) as other documents and literature in the review.

Regarding the type, amount, scope, and level of priority given to Action Plan-related information on the Web sites, each varied by organization. Although we found a great deal of information on HAIs, information on the Action Plan was not as widespread. Of the agencies listed above, only OPHS has a specific section dedicated to the Action Plan.

Both the AHRQ and CDC Web sites have extensive information on HAIs such as activities that support the reduction of HAIs and the measure and annual rates of decrease in incidences of HAIs. There were many downloadable fact sheets, press releases, and links to other agencies and organizations interested in HAIs. The CDC home page has a link to MRSA-related information. The MRSA link breaks down information about prevention, data, and statistics. There is also a link for all HAIs, with specific information on ARRA funding, State plans regarding HAIs, and HAI rate estimates.

The CMS Web site has little information directly related to the Action Plan itself. The information on the site is mostly related to ongoing efforts described in the Oversight and Incentives chapter of the Action Plan. There is a considerable amount of information on Federal health and safety requirements, links to reporting codes, Hospital Compare information, and descriptions of ARRA funding. Because the information is regulatory, medical facilities (hospitals, ambulatory centers, etc.) and other parties that need to know specific details of the different programs would find this information more useful than the general public.

Finally, the OPHS Web site has the most information regarding the Action Plan. The Action Plan itself can be downloaded from this Web site as well as guidance given to the States in developing State Action Plans. Here can also be found presentations from the working groups regarding the outcome of meetings and the summary of input from the stakeholders on the revision of the Action Plan.

3.1.2 Sample Selection and Analysis Plans for the Document and Literature Review

Each document included in the document and literature review was briefly scanned to determine if, and to what degree, the document contained information on the following evaluation topics: historical context for the Action Plan, policy context, descriptions of pre-Action Plan initiatives, the Action Plan development process, implementation and progress, HAI data and monitoring (two subcategories), knowledge development (two subcategories), infrastructure development (five subcategories), HAI prevention and practice adoption (two subcategories), and leadership and strategy. The results of this scan were recorded in an Excel table along with reference information about the document, the method by which the document was identified, and a brief summary of the document and/or notation regarding the document's relevance to the Action Plan.

Exhibit 8 summarizes the number of documents with a significant focus on the evaluation topics by categorizing the documents into three types. First, we reviewed 30 journal articles, the majority of which were from peer-reviewed journals. Second, we reviewed 78 internal organizational documents, which were provided to us by participants in the Action Plan and by external stakeholders. Examples of organizational documents include meeting minutes, draft reports, and presentations given at stakeholder meetings. Third, we reviewed 113 published documents and online materials. Examples include publicly available reports from HHS agencies and other organizations, legislation, legislative testimony, and Web site content. (It should be noted that in the case of technical documents pertaining to NHSN and HAI prevention plans submitted by States, these two sets of documents were counted as two documents, rather than counting each document individually.)

Many of the documents included in this review will also be used as part of the Process evaluation, the next phase of our work. For example, the meeting minutes from the Action Plan Steering Committee and the working groups provide valuable insight into the Action Plan development (i.e., Input Evaluation) and implementation (i.e., Process Evaluation).

Exhibit 8: Number of Documents with Significant Content Related to Evaluation Topics

Evaluation Topics	Journal Articles	Internal Organizational Documents	Published Reports and Other Publicly Available Material
Historical Context	2	2	9
Policy Context	0	5	16
Description of Pre-Action Plan Initiative/Program	6	3	25
Action Plan Development Process	0	27	15
Action Plan Implementation and Progress	0	52	21
HAI Data and Monitoring (Integrated data systems for monitoring adoption, Outcomes measurement and monitoring)	25	42	66
Knowledge Development (Epidemiology of HAI, Evidence for practice effectiveness)	25	9	55
Infrastructure Development (Regulatory Oversight, Incentives, Training, Support Structure, Tools)	26	42	120
HAI Prevention Practice (Agency HAI prevention and change activities, Provider HAI prevention and change activities)	14	26	60
Leadership and Strategy	8	26	13

* Documents were counted multiple times if they focused on more than one evaluation topic.

Following the first-level scan of each document, the documents that best supported and supplemented our data collection activities were selected for further review. These documents were fully read by multiple team members.

3.1.3 Strengths and Limitations of Methods for the Document and Literature Review

Strengths. There are four primary strengths of the methods used for the document and literature review. First, because the majority of the documents and literature included in the review were recommended to us by individuals directly involved in developing and implementing the Action Plan, we have a high degree of confidence that these documents are the most relevant ones available to understand the context that led to and influenced the development of the Action Plan. Second, the documents and literature come from a wide range of sources, not just from the organizations directly involved in implementing the Action Plan. Therefore, they contribute a broader range of information than we could collect during the interviews and serve as an important supplement to the interview findings. Third, our ability to review the meeting minutes of the Action Plan Steering Committee and working groups offers a nearly first-hand account of the strategic processes that took place between

stakeholders involved in developing and implementing the Action Plan. Fourth, because many of the documents and literature shared by Action Plan stakeholders relate to activities that are being conducted as part of the Action Plan, our collection of documents and literature provides a strong foundation to begin work on the Process evaluation.

Limitations. The primary limitation of the methods used for the document and literature review is that they did not involve a systematic, comprehensive or exhaustive literature search on HAI prevention. The documents and literature were identified through a purposeful sampling strategy that employed limited criteria for sources of documents and literature and for inclusion. The implication of this limitation is that our knowledge about specific prevention practice research may be limited. Additionally, if HAI prevention activities relevant to the Action Plan were conducted by organizations not involved in the Action Plan, or not known to Action Plan stakeholders, our knowledge of those activities is limited.

3.2 Stakeholder Interviews

Stakeholder interviews were planned and implemented with a sample of participants to supplement the document review and gain a broad perspective on an array of issues related to the context of the Action Plan's development and the subsequent inputs associated with its initiation and early efforts. Consistent with the notion of a formative evaluation, our goal in developing the sampling frame was to create a process that would result in a sample that could provide a range of perspectives from stakeholders engaged with the Action Plan. By capturing the range of perspectives, the IMPAQ/RAND team attempted to gather information to allow feedback across a broad spectrum of stakeholders even when resources limited the number of interviews that could be conducted. Both the sampling frame and the interview protocols were designed to capture both mainstream and alternative viewpoints for consideration.

3.2.1 Sampling Frame Development

The number of interviews that could be conducted in this phase of the evaluation was limited due to several factors including resources, timeline for the first phase of the evaluation, and Paperwork Reduction Act considerations. In response to this constraint, we engaged in a very careful set of processes to develop the sample frame.

To begin the process, we independently reviewed the Action Plan and developed an initial list of individuals and organizations that were noted as participants in the development of the Action Plan or that had been involved in HAI-related work that was cited in the plan. This diverse set of potential participants brought different perspectives about the context and input of the Action Plan. Next, we conducted brief pre-interview discussions by telephone with members of the HHS Federal Agency Working Group (FAWG) for the Action Plan evaluation to obtain their input about which individuals within their organizations would be appropriate contacts to speak to about the context, development, and implementation of the Action Plan, which external organizations or perspectives they thought would be important to capture, and

whether they had specific recommendations for contacts we might speak to in these organizations.

With this additional input, we developed a master sampling frame. This list contained over 80 different contacts, organizations, or types of organizations from which we might sample (see **Exhibit 3.2**). Taking into consideration the input received from the FAWG members, we combined some of the categories and settled upon two broad groupings of participants. One group consisted of representatives of the Federal agencies that were signatories to the Action Plan (e.g., on the Steering Committee or the working groups); we sampled many, though not all possible agencies. The second group consisted of additional stakeholders, including other Federal agencies, consumer and patient advocacy groups, insurers and purchasers, health care provider and industry associations, health care improvement and accreditation organizations, and academic and research institutions.

From these groups, we ranked the potential participants as high, medium, or low priority based on the extent to which potential participants could represent important stakeholders or perspectives for the context and input portion of the evaluation. We then selected interview participants to invite from among those identified as high priority. Where possible, we tried to include at least two participants from each of these additional perspectives (in some cases one person might have represented more than one role). While conducting the interviews, we asked interviewees for suggestions of additional individuals who might also be informative during the evaluation. Through this snowball approach, we added a few additional potential participants to our master sampling frame. We selected from this group of additional participants as a way of rounding out the perspectives and experience represented by the other interviewees.

3.2.2 Protocol Development

After we finalized the sampling frame, we developed protocols for the different types of organizations we expected to interview. The protocols generally consisted of a core set of questions on the following topic areas:

- Antecedent and historical context;
- Development of the Action Plan;
- Current role in the Action Plan activities;
- Current status and context;
- Opportunities and challenges of preventing or reducing HAIs; and
- Future directions.

In addition, unique protocol questions were developed to interview each type of stakeholder, yielding seven unique protocols. For example, the protocol for academic and research institution representatives included questions regarding what they perceived to be the biggest

implications of the Action Plan for researchers, and protocols for purchasers and insurers focused on the issues from their perspective. Protocols were reviewed internally by the interview leads and then circulated to the IMPAQ/RAND team for review and comment before being finalized. Prior to beginning the interview process, the protocols (including the informed consent and confidentiality procedures) were submitted to RAND's Institutional Review Board (IRB) for review and approval, which served as the IRB of record for both RAND and IMPAQ. The protocols were not submitted for OMB clearance, since there were no more than nine informants per tailored protocol for each non-Federal stakeholder group (see **Exhibit 3.2**). In addition, not all questions were asked of each interviewee within a group; rather, the goal was to cover all topics across the interviewees for a stakeholder group, focusing for a particular interviewee on those topics about which he or she was most knowledgeable. Example protocol questions are provided in Appendix B.

3.2.3 Inviting Participants and Conducting Interviews

The IMPAQ/RAND team first contacted potential interview participants by e-mail to request an interview and explain the study. The e-mail invitation included a letter in support of the study from Dr. Donald Wright, Deputy Assistant Secretary for Healthcare Quality. A copy of this letter is provided in Appendix C. Next, a member of the IMPAQ/RAND team followed up with potential participants by telephone to finalize the interview scheduling. Each interview was scheduled for 1 hour. Given the diverse geographic spread of the interview participants, most of the interviews were conducted by telephone. However, when possible, the IMPAQ/RAND team conducted some interviews in person at the participant's place of work.

Each interview was conducted by two members of the interview team, one lead interviewer and one note-taker to record detailed notes of the interview. Each interview began with a brief description of the study and review of IRB language to obtain informed consent. Upon receiving consent to continue, the interviewer conducted a semi-structured interview using the appropriate protocol. Consistent with the semi-structured nature of the interviews, the protocol was used as a guide, but the interviewer had some flexibility to follow up on interesting discussion points. Given time constraints and the semi-structured nature of the interviews, not all questions were asked of each participant, although the vast majority were asked a core set of questions for consistency. Following the interview, the notes (generally taken verbatim) were typed and deposited on a password-protected shared workspace. The lead interviewer for each interview reviewed the notes for accuracy before finalizing them. Then they were made available for review and analysis by the IMPAQ/RAND team.

In total, we conducted 27 interviews between January and June 2010. One person did not respond to requests for an interview. Thirteen of the interviews were conducted with representatives of Federal agencies that officially participate in the Steering Committee or the working groups, and the remaining 14 interviews were conducted with representatives from the various additional external stakeholder groups. **Exhibit 9** shows the total sampling frame and number of interviews conducted by type of stakeholder organization. The "total sampling frame" column gives the number of individuals from each category of stakeholder organization

who were identified as potential interview participants through the review of the Action Plan, pre-interviews with FAWG members, or snowballing. (In some cases, multiple potential interview participants from the same organization were identified.) We selected participants to invite from among this group. The “number of interviews” column in the table gives the specific number of interviews conducted with participants from the various stakeholder types. Some interviews included more than one respondent. As described above, separate interview protocols were developed for each stakeholder type, and no protocol was used for more than nine non-Federal participants. We attempted to include at least two participants for each category (an exception was that only one “Other Federal Agency” representative was interviewed, in part because some agencies in this category came to participate in the Action Plan only later).

Exhibit 9: Interview Sampling Frame and Interviews Conducted

Stakeholder Type	Total Sampling Frame*	Number of Interviews
Stakeholder Type	Total Sampling Frame*	# of Interviews
Federal Agencies Participating in the Action Plan	35	13
Other Federal Agencies	5	1
Health Care Provider and Industry Associations	21	4
Health Care Improvement and Accreditation Organizations	5	3
Consumer and Patient Advocacy Organizations	10	2
Purchasers and Insurers	3	2
Academic and Research Institutions	5	2
Total	84	27

* Includes numbers of individuals identified in each stakeholder category.

We were aware that during the development of the Action Plan OPHS had held a series of stakeholder meetings to obtain input from external stakeholders. Our interviews differed from those meetings in three key ways. First, we drew a purposive sample to capture a broad range of stakeholder perspectives by specifically inviting participants. Second, we explicitly included a substantial number of representatives from the Federal agencies that were signatories to the Action Plan, to obtain their perspective on such questions as the context, development, and implementation of the Action Plan, and the interaction between agencies, rather than focusing solely on external stakeholder perspectives. Finally, the 1-hour, individual nature of the interviews was a very different setting from a larger stakeholder meeting and allowed for in-depth perspectives. Moreover, the more intimate setting may have made participants more comfortable expressing their views than they might have been in a public forum.

3.2.4 Analysis Method

The analyses of the interview data were conducted in an iterative manner and included analyses of sections of the protocol and the broad topics covered; we then conducted an overall analysis across topics. A lead interviewer reviewed each set of notes for content on a particular set of topics to identify themes. In addition, a designated backup reviewer from the IMPAQ/RAND team served as a second independent reviewer to check the themes identified by the lead reviewer and minimize any idiosyncratic readings of the data. Next, the process was opened to the entire IMPAQ/RAND team, which had the opportunity to review the interview notes and themes and provide comments.

Themes were identified by the team in a number of ways. First, we identified a theme if there was a modal or most common response to a given topic. Next, in cases where there was no consensus, responses given by several participants that formed clusters were identified as potential themes. In addition, we highlighted interesting “minority viewpoints” that might have been expressed by only a few people but were identified as significant, given their bearing on the Action Plan or their representation of a particular perspective.

We also analyzed the data to examine similarities or differences between the representatives of the Federal agencies that were signatories to the Action Plan and the additional stakeholders external to those agencies. Where differences emerged, these were noted in the analysis.

3.2.5 Strengths and Limitations of Interview Methods

The interview process had a number of core strengths that contributed to obtaining high quality information from participants. First, the interview sampling frame was carefully developed through the document review, pre-interview, and snowballing methods to identify a reasonably comprehensive list of stakeholders within the Federal agencies involved in the Action Plan and the additional stakeholder groups. Second, the selection of sampling frame candidates to invite for interviews was diverse, including representatives from the key Action Plan agencies and external stakeholders. Third, the rate of participation was exceptionally high. Of those invited to participate, no one declined to participate, and only one person did not respond to the request. Fourth, interview protocols were as comprehensive as possible given the length of the interviews. Protocols covered a range of topics about the context and inputs to the Action Plan, as well as challenges and future directions. Finally, the analysis process enabled us to identify both majority viewpoints and pertinent minority perspectives about the Action Plan and to identify where the perspectives of the Federal agencies varied from those of external stakeholders.

Nevertheless, as with any method, several potential limitations of the interview processes must be considered. First, for a variety of reasons (including resources and Paperwork Reduction Act considerations), it was possible to conduct only a limited number of interviews. As a result, we could not interview representatives from every Federal agency that was a signatory to the Action Plan or all potential additional stakeholders. We purposefully prioritized which agencies

and stakeholders to invite based on those most critical to hear from at this stage of the Action Plan's development and implementation, and at this phase of our study. For example, we prioritized agencies most heavily involved in the development of the Action Plan, stakeholders familiar with its development and revision, and those involved in early implementation efforts. In addition, we tried to incorporate a range of perspectives and at least two interview participants in each stakeholder category. While our interview sample was not designed to be fully representative, it did include a wide array of participants and organizations, reflecting a broad range of perspectives about the Action Plan.

A second limitation of the interviews was that the length of the interviews was 1 hour. This necessarily limited the level of detail it was possible to cover about each of the topics we examined.

Third, as mentioned above, interviews were conducted during the first half of CY 2010. Therefore, these interviews capture the perspectives of the participants related to the Action Plan at this point in time. Since this is a formative evaluation of an ongoing initiative, the work on the Action Plan progressed during the course of our interviews and continued following these interviews. Therefore, the results presented here should be considered a snapshot in time of an active process that continues to evolve as the work of the Steering Committee and the working groups progresses.

These limitations notwithstanding, the information contained in this report represents as thorough and objective an evaluation of the context and inputs to the Action Plan as possible. We believe this information will be useful in planning the activities and evolution of the Action Plan as it moves forward.

3.3 Baseline Data Inventory and Recommendations

During the first year of the evaluation, the IMPAQ/RAND team also conducted a baseline inventory analysis of HHS data systems related to HAIs as part of the Product evaluation component of the CIPP evaluation model (see Chapter 1).¹¹ Documenting and analyzing the characteristics, strengths, shortcomings, and potential uses of the HHS data systems capable of detecting HAIs and prevention processes is a valuable endeavor. The research community, policymakers, and consumers need information about HAIs to study patient safety issues, develop policy, and make informed personal health care choices. An inventory that describes the available data systems along a number of important dimensions can be used to inform future efforts to collect and disseminate information about infection rates and HAI prevention process implementation to these and other stakeholders. Moreover, the evaluation team's charge was similar to and overlapped with one of the priority recommendations made in the Action Plan by the Information Systems and Technology Working Group. The working group recommended the creation of a "comprehensive HAI database inventory to guide future plans for near-, mid-, and long-term integration and interoperability projects and to establish the extent of definitional alignment and data element standardization needed to link HAI data across the nation."⁶ In addition to documenting the various surveillance methodologies and

definitions used in the data systems, the inventory can be used as a tool to assist policymakers and stakeholders to understand future data needs for HAI monitoring. One possibility, for example, is that the inventory will reveal useful features of some data sets that can be incorporated into others.

The IMPAQ/RAND team communicated the methods, results, and recommendations from the first year's product evaluation in an Interim Report on Baseline Measures, Inventory, and Recommendations, which was submitted to the project officer, members of the FAWG, the HHS Steering Committee, and the Evaluation Working Group in June 2010. In response to their comments, we revised the Interim Report. Brief summaries of the methods and findings from the first year's data inventory product evaluation are incorporated into the present document; the reader is referred to the Interim Report for more detailed information. See also Appendix D for a summary of the data inventory Interim Report's findings." ¹¹

4. CONTEXT EVALUATION RESULTS

In this chapter, we report the results of the Context evaluation. The goal of our Context evaluation was to identify and describe the factors that motivated HHS to embark on the Action Plan initiative and that set the stage for what the Action Plan would encompass. Specifically, we conducted four evaluation tasks for the Context evaluation:

- Document and assess contextual factors;
- Document the Congressional and legislative intent for the initiative and the funding provided;
- Assess mandates and requirements for HHS; and
- Characterize the effects of these contextual factors on HHS strategy in creating the plan.

The results reported in this chapter reflect the perspectives of the Federal agency personnel and other stakeholders as obtained from our interviews and supplemented with information gathered from our document and literature reviews. We drew from both sources of data to provide a high-level perspective of forces and events that led to the creation of the Action Plan and helped form the requirements and expectations within which the Action Plan operates and upon which it will be judged by those responsible for oversight and by its varied stakeholders.

This chapter is organized according to key themes in three areas: (1) the antecedents and catalysts of the plan (2) legislative and regulatory processes for oversight and funding, (3) and policy mandates and expectations.

4.1 Overview of Key Findings

- The Context assessment identified three historical forces that drove the creation of the Action plan: advances in knowledge about HAIs produced by the epidemiological and infection control community for more than a decade; more recent public awareness campaigns spearheaded by consumer groups advocating on behalf of patient rights; and the patient safety movement that drew attention to HAI issues in the early 2000s. These forces culminated in a 2008 report by GAO that was widely recognized as the catalyst for the development of the Action Plan—*Health-Care-Associated Infections in Hospitals: Leadership Needed from HHS to Prioritize Prevention Practices and Improve Data on These Infections*.¹ The subsequent Congressional hearings related to the GAO findings set the stage for change within HHS and resulted in policy and funding to support the Action Plan.
- The Action Plan's development was shaped, supported, and funded through a variety of legislative and regulatory policies at the Federal level. In the Omnibus Appropriations Act of 2009, Congress appropriated \$5 million to HHS to develop the Action Plan, with continued annual appropriations to support its coordination, particularly by OPHS. Other specific legislative and regulatory changes have focused on HAI-related activities.

Key CMS programs targeted by these policies include the Conditions of Participation (CoP) for hospitals participating in Medicare, the emerging system for Value-Based Purchasing (VBP), and the 9th Statement of Work (SOW) for Quality Improvement Organizations (QIOs), funded by CMS to assist Medicare-reimbursed health care organizations improve the quality and efficiency of their services. Two other specific legislative and regulatory programs have focused on HAI-related activities: the recently created patient safety organizations (PSOs) administered by AHRQ and the ongoing Healthy People initiative involving all HHS agencies.

- A number of mandates—that is, unofficial but widely shared and strongly held expectations—surrounded development of the Action Plan. Some of these resulted from direct legislative mandates, and others occurred as part of the policy development process. These mandates have shaped environment within which the Action Plan operates and created expectations about its performance that will influence how it is judged. Two of these could be considered paramount: (1) that the Action Plan would attempt to reduce duplication of effort within HHS and across the Federal government and (2) that the Plan would include a strategy for coordination of HAI prevention efforts and resources across government at the Federal, state, and local levels.

4.2 Historical Antecedents and Catalysts of the Action Plan

Healthcare-associated infections are by no means new. Awareness of HAIs and efforts to prevent them have been in place for many years. In exploring the events leading to the Action Plan, interviewees consistently identified three historical forces that contributed to increasing interest in HAIs and prevention efforts. Those historical forces were the actions of three distinct groups: the epidemiological and infection control community, consumer advocates, and participants in the patient safety and improvement movement. These historical forces led to an event that was widely recognized as the proximate catalyst for the development of the Action Plan—a report by the Government Accountability Office (GAO), in March 2008, requested by Congress, titled *Health-Care-Associated Infections in Hospitals: Leadership Needed from HHS to Prioritize Prevention Practices and Improve Data on These Infections*.¹ The subsequent Congressional hearings related to the GAO findings set the stage for change within HHS and resulted in policy and funding to support the Action Plan.

4.2.1 Epidemiological and Infection Control Communities

Many of the Federal and other stakeholders we interviewed emphasized that decades before the current spotlight on HAIs in health care, the epidemiological and infection control communities had been working on this issue. These communities have generated the basic scientific understanding available on the microbes and pathology associated with HAIs, the current public health surveillance systems and methodologies for monitoring HAI rates, and a host of guidelines and prevention practices that constitute much of the current HAI prevention “toolkit.” Some interviewees from these professions noted frustration that the long-standing work of the professionals from these communities, some of whom “devoted their whole

career” to the topic of HAIs, has tended to go unrecognized and “escaped the people who have come to the problem more recently.”

Reflecting the range of prevention guidelines and interventions that have been developed by the epidemiological and infection control communities, a task force of leading experts from the Society for Healthcare Epidemiology of America (SHEA) and the Infectious Diseases Society of America (IDSA) compiled a compendium of HAI prevention strategies for use in acute care hospital settings, which was published just prior to the release of the Action Plan. The compendium highlights the breadth and specificity of existing practice recommendations and is intended to facilitate implementation of those practices.¹²

Despite the long history of epidemiological and biomedical research and development of prevention guidelines and practices, three of the main professional infection control and prevention organizations—SHEA, IDSA, and the Association of Professionals in Infection Control (APIC)—have identified important and persistent gaps in knowledge. These gaps include evidence on the pathogenesis of specific microbes across different settings, the effectiveness of screening strategies, and antimicrobial stewardship (see also Chapter 6). Based on the extent of these deficiencies, these associations have explicitly stopped short of recommending mandatory implementation of infection control practices that have been developed to date, arguing that any national HAI prevention effort “should begin with the following priorities: scrutinizing the science base, developing a prioritized research agenda, conducting studies that address the questions that have been identified, creating and deploying guidelines that are based on the outcomes of these studies, and then initiating studies that assess the efficacy of the interventions.”¹³

HHS agencies also featured prominently among the main contributors to the foundational work in HAI surveillance and prevention and as collaborators with the epidemiology and infection control communities. In particular, CDC was recognized by many interviewees as the Federal agency with the largest and longest focus on HAIs. As one interviewee stated, the “majority of the charge [for working on HAIs] was singularly led by the CDC,” which has done “as well as they could within the confines of their budget.” CDC’s HAI-related efforts have primarily covered three areas:

- Building knowledge about how to prevent HAIs;
- Developing prevention strategies and guidelines; and
- Developing data collection systems.

Key examples of CDC’s work on HAIs include:

- The agency’s publication in 1985 of results from the Study on the Efficacy of Nosocomial Infection Control (SENIC) Project,³ considered a milestone HAI initiative.¹² According to one interviewee, it was one of the first published studies to capture attention on HAIs.

- The establishment of the Prevention Epicenters Program in 1997, in which CDC and academic institutions partner to conduct research on HAI prevention, antimicrobial resistance, and other health care-related adverse events.²
- Collaboration between CDC and the Healthcare Infection Control Practices Advisory Committee (HICPAC) to develop and disseminate evidence-based guidelines to the health care community about recommended HAI prevention strategies and practices.³ These include the Prevention of Surgical Site Infection, Hand Hygiene in Healthcare Settings, Prevention of Intravascular Catheter-Related Infections,¹⁴ and Preventing Healthcare-Associated Pneumonia.
- The establishment of the National Nosocomial Infections Surveillance (NNIS) System in 1970, restructured in 2005 as the National Healthcare Safety Network (NHSN), to conduct wide-scale tracking of epidemiological trends in HAIs, and to support monitoring of HAI practices and outcomes at the individual facility level.⁴

4.2.2 Consumer Advocates

While professionals working in the infection control arena have focused on HAIs for decades, HAIs have become a highly visible issue to policymakers and the public only within about the last 10 years, according to most of our interviewees. In a view common to the majority of stakeholders external to the Action Plan, one interviewee described a “shift,” as greater awareness of HAIs developed, “in the responsibility from health care facilities alone to a shared responsibility that involves public health in a formal, governmental kind of way.” Stakeholders we interviewed from a wide variety of perspectives attributed a large degree of this “bump” in awareness to consumer advocates, whose efforts have played a significant role in raising the priority of HAIs as a public and personal health issue and in stimulating policies and resources devoted to monitoring and preventing HAIs.

According to our interviewees, some of the interest and strong advocacy on the part of consumers has been fueled by the increasing prevalence of HAIs, including the emergence of antimicrobial- and antibiotic-resistant infections, often referred to as “superbugs,” such as methicillin-resistant *Staphylococcus aureus* (MRSA). A strong connection was also noted between the roles that consumers have played in increasing awareness of HAIs and the attention paid to the issue by the popular media (local and national news outlets for television, newspapers, magazines, and radio).

Among the many consumer groups involved in HAI issues, Consumers Union (CU) has taken a lead role in spearheading HAI prevention efforts and in helping organize the efforts of other consumer representatives on the topic. CU and other consumer groups have actively worked with the media to provide credible and reliable information on HAI prevention. As described by

² See details at <http://www.cdc.gov/ncidod/dhqp/epicenter.html>.

³ See details at <http://www.cdc.gov/hicpac/>.

⁴ See details at <http://www.cdc.gov/nhsn/index.html>.

several interviewees, their campaigns have been heavily media-based and have helped “put the human face on this problem.”

Since the mid-2000s, CU has mounted an ongoing campaign on preventing HAIs.⁵ At the core of the campaign is a belief in the importance of public reporting of hospital infection rates as a way to prevent HAIs and increase public awareness of the issue. In particular, CU has focused on a state-by-state strategy of encouraging the adoption of HAI surveillance systems. Initially, CU developed a model bill for the adoption of hospital infection reporting programs and engaged consumers in contacting their legislators about adopting such a bill. According to one interviewee, responses to the campaign’s early activities were a welcome surprise; 30 States filed the model bill or legislation similar to it. In 2003, Illinois became the first State to enact mandatory reporting.¹² By 2008, the GAO found that 23 States had implemented mandated HAI public reporting systems. Of these, 20 States used the CDC’s NHSN as their data collection system,¹⁵ which, as noted by several interviewees, points to the interrelation of the different forces for HAI prevention (i.e., the efforts of consumer groups in conjunction with the epidemiological and infection control community, including CDC). In addition, CU has promoted hospital-level public reporting of HAI indicators on its own HAI campaign Web site as well as through collaboration with others.⁶

4.2.3 Patient Safety and Improvement Movement

The third historical force leading to the development of the Action Plan was the uptake of HAIs as a priority issue within the patient safety and improvement movement. A number of interviewed stakeholders noted that the patient safety movement’s attention to HAIs has occurred relatively recently. For example, the Institute of Medicine’s 1999 landmark patient safety report, *To Err is Human*,¹⁶ contained only minimal references to HAIs. Since that report’s publication, however, the patient safety movement has become very influential in HAI prevention policy and practice. A key turning point, dated to the early 2000s by the interviewees, occurred when attention began to focus on safety-related research that demonstrated how HAI prevention practices could be successfully implemented. For example, the “bundling” of sets of evidence-based practices was noted to be associated with substantial reductions in the incidence of HAIs. Several interviewees indicated that prior to that time, most health care professionals considered “a certain level of infections as acceptable” and inevitable, and the ability to successfully implement HAI prevention practices with any degree of sustainability or scale as largely elusive. Studies such as the Michigan Keystone Project, which targeted central-line associated bloodstream infections (CLABSI) in ICUs,¹⁷ “told us that our ‘normal’ would need to change.” Interviewees interpreted this to mean that the level of HAIs that health professionals, policymakers, and the public would tolerate would have to drop far below the level accepted prior to the early 2000s “turning point.”

⁵ See details at <http://www.safepatientproject.org/topics.html>

⁶ See, e.g., www.stophospitalinfections.org and <http://www.whynotthebest.org/pages/methodology>.

The shift toward considering a large proportion of HAIs to be the result of errant, and potentially correctable, medical care processes brought the issue more directly under the umbrella of the patient safety movement, with HAI prevention practices and indicators becoming integrated into a variety of health care safety and improvement initiatives. Major examples of these initiatives include the Institute of Healthcare Improvement's (IHI) 100K and 5 Million Lives Campaigns,⁷ the National Quality Forum's Patient Safety Standards,⁸ the Leapfrog Group's hospital quality survey and reporting initiative,⁹ and the Joint Commission's National Patient Safety Goals.¹⁰ Both Federal and external stakeholders to the Action Plan alluded to the role of HHS in helping to further a safety agenda around HAIs, with particular emphasis on AHRQ's funding of research on the implementation and dissemination of HAI prevention practices, such as the CLABSI studies noted above.

Other external stakeholders we interviewed indicated how the patient safety and improvement movement helped to raise the visibility and status of HAI control and prevention issues among executive-level decision-makers within health care organizations. That, together with growing evidence of HAI prevalence, patient consequences, and costs,¹⁸ has helped HAIs to become one of the most prominent safety issues or, as one interviewee put it, "the poster child of the patient safety movement."

4.2.4 Configuration of Historical Forces

According to the accounts from the interviewees and the documents we reviewed, these historical forces leading to the Action Plan appear to have operated with a cumulative and reinforcing effect, with all three continuing to contribute key resources, provide infrastructure, and drive and influence changes towards preventing HAIs. This configuration of forces differentiates HAIs to some degree from other patient safety issues. First, the involvement of consumer groups and advocates, who have played a long-standing and influential role in HAI prevention efforts, has been harder to generate and sustain for other patient safety issues. Second, some underlying tensions persist between the major sets of forces in HAI prevention. One is between consumer groups and the other two stakeholder groups as consumer advocates alternately debate and collaborate with health care providers and policymakers. The second, and perhaps more distinctive tension, is between the epidemiological/infection control and the safety/improvement communities, which came to the HAI arena at slightly different times and with somewhat different perspectives, strategies, and approaches, as we discuss in greater detail in later chapters.

⁷ See <http://www.ihl.org/IHI/Programs/Campaign>.

⁸ See <http://www.qualityforum.org/Topics/Safety.aspx>.

⁹ See <http://www.leapfroggroup.org/>.

¹⁰ See <http://www.jointcommission.org/patientsafety/nationalpatientsafetygoals/>.

4.3 GAO Report: Catalyst of the HHS Action Plan

Nearly all stakeholders indicated that the GAO Report released in March 2008 and subsequent Congressional hearings^{1,19} constituted the set of events that launched the development of the Action Plan. Partly a result of the historical forces described in the previous sections, as well as an instance drawing them together, the GAO report and hearings were highly critical of HHS's efforts to coordinate the agency's HAI-related efforts. Several Action Plan agency representatives we interviewed reported that, prior to the GAO report, there was a growing realization within HHS that the agency needed to better coordinate HAI measurement and prevention efforts among its operating divisions. The report provided the spark for action to address those concerns and signal to stakeholders within and outside of HHS that the department would prioritize efforts and collaborate in a more strategic manner around HAI issues.

The initial request to the GAO to investigate these issues came from Congressman Henry Waxman, then Chairman of the House Committee on Oversight and Government Reform. According to interviewees, Congressman Waxman and his staff had long followed the public and consumer health concerns with HAIs and had conducted a significant amount of research on the issue prior to requesting the GAO report. The request asked the GAO to report on the following programs within HHS:

1. CDC's guidelines for hospitals to reduce or prevent HAIs and what HHS does to promote the guidelines' implementation;
2. The Centers for Medicare & Medicaid Services (CMS) and hospital accrediting organizations' required standards for hospitals to reduce or prevent HAIs and how compliance is assessed; and
3. HHS programs that collect data related to HAIs and integration of the data across HHS.

As part of its examination, the GAO reviewed documents and interviewed representatives from HHS agencies (CDC, CMS, AHRQ, and FDA) as well as infection control experts from outside the government, including representatives from organizations such as SHEA, APIC and the World Health Organization (WHO).¹

The GAO report, which focused on HAI prevention efforts for acute care hospitals, was critical of several aspects of HHS's efforts. The main findings and recommendations/implications are summarized in **Exhibit 10**.

Exhibit 10: Findings, Recommendations, and Implications of the GAO Report, March 2008

Finding	Recommendation /Implication
<p>1. Multitude of strongly recommended prevention practices inhibits implementation by health care organizations and providers.</p> <p>Of the approximately 1,200 HAI prevention clinical practices contained within CDC’s 13 hospital infection control and prevention guidelines at the time of the GAO investigation, over 500 of the practices were strongly recommended by CDC. CDC and AHRQ had conducted activities to promote the adoption of practices but, despite the potential worthiness of these activities, the GAO determined that they were established without being guided by clear prioritization of the practices.</p>	<p>1. Identify priorities among CDC’s recommended practices and determine how to promote implementation of the prioritized practices.</p> <p>HHS should issue priorities for prevention practices and follow those priorities in terms of conducting HHS agencies’ own activities, including deciding to include priority practices in CMS’s Conditions of Participation (CoP) for hospitals participating in Medicare.</p>
<p>2. Data on HAIs are fragmented across HHS agencies in databases that do not consistently define measures or interoperate.</p> <p>According to the GAO, most data on HAIs were reported by HHS agencies in four separate databases.* For this reason, no single source of information showed the incidence and location of HAIs, and no mechanism existed for integrating or linking the data within the databases to produce a complete view of the HAI problem.</p>	<p>2. Establish greater consistency and compatibility of the data collected across HHS on HAIs to increase information available about HAIs, including reliable national estimates of the major types of HAIs.</p> <p>Potential ways to improve the interoperability of data systems include establishing common definitions or “crosswalks” of measures that relate data fields across the various databases, and creating common patient identifiers in the different databases so that data on the same individuals found in multiple databases could be pulled together.</p>
<p>3. HHS lacks department-wide coordination of HAI prevention efforts.</p> <p>A common theme across the GAO report was that while there has been relatively good communication across the HHS agencies regarding HAI-related activities, a number of complementary efforts could be better coordinated. Additionally, some efforts are duplicative. For example, both CDC and AHRQ independently reviewed scientific evidence on the effectiveness of HAI prevention practices without any reference to other agencies’ efforts. According to the report, one HHS official told GAO staff that “no one within the office is responsible for coordinating infection control activities across HHS.”</p>	<p>3. Instill better coordination of HAI activities across HHS agencies.†</p> <p>Although the GAO report only included the two formal recommendations above related to prioritizing CDC prevention guidelines and improving interoperability of data systems, it makes clear references to the need for better mechanisms or procedures to coordinate action across HHS agencies in these areas.</p>

Note: Adapted from *Health-Care-Associated Infections in Hospitals: Leadership Needed from HHS to Prioritize Prevention Practices and Improve Data on These Infections*, GAO, March 2008.¹

* CDC’s National Healthcare Safety Network (NHSN), CMS’s Medicare Patient Safety Monitoring System (MPSMS), CMS’s Annual Payment Update (APU) program, and AHRQ’s Healthcare Cost and Utilization Project (HCUP).

† Not a formal recommendation of the GAO report.

In its written comments to the GAO report¹ and in testimony at the hearings,¹⁹ HHS agreed with most of the GAO recommendations and offered examples of actions the department planned to take in response to the recommendations, such as a joint review by CMS and CDC to prioritize recommendations for infection control practices and to explore ways to better link agency databases that collect information on HAIs. These actions formed the basis of activities for what would become the HHS Action Plan to Prevent Healthcare-Associated Infections.

The testimony at the hearings sent a clear message that HHS was not doing enough to prevent HAIs. Following that experience, and in response to the question “where do we go from here?”, the HHS Deputy Secretary tasked the Office of Public Health and Science (OPHS) to convene a Steering Committee for the prevention of HAIs, to address the concerns and recommendations made in the GAO report. The Deputy Secretary of HHS named Donald Wright, MD, MPH, at that time Principal Deputy Assistant Secretary for Health, who had testified at the Congressional hearings on behalf of HHS, to lead the Office of Healthcare Quality (OHQ). OHQ was given primary responsibility for coordinating the activities of the Steering Committee. As a way of guiding its efforts, the Steering Committee decided to develop an Action Plan.⁶

Between the release of the GAO report in March 2008 and the release of the Action Plan in June 2009, Congress held one hearing and the GAO issued two additional HAI-related reports. These reports focused on narrower issues related to HAIs, including an overview of State HAI reporting programs and individual hospital initiatives to reduce HAIs¹⁵ and HAIs related to medical devices.²⁰

In the year following the release of the Action Plan, the GAO released a report focusing on HAIs in ambulatory surgical centers,²¹ and gave written testimony assessing the ability of elements of the Action Plan to address the concerns and recommendations raised in the March 2008 report.² This testimony noted uncertainty at that time regarding the likelihood of the Action Plan being adopted in its current or revised form because of the impending change in the presidential administration.

4.4 Legislative Oversight, Funding, and Regulatory Expectations

4.4.1 Policy Changes and Funding

From the beginning, the development of the Action Plan has been shaped, supported, and funded through a variety of legislative and regulatory policies at the Federal level. As programs and projects related to the Action Plan have been funded, primary Congressional oversight for Action Plan activities has moved from the House Oversight and Government Reform Committee to the House Appropriations Committee.

As summarized in **Exhibit 11**, Congressional funding and directives for activities encompassed in the Action Plan derive from the annual Omnibus appropriations bills for HHS agencies, as well as specific HAI, health care, and other Federal legislation.

In the Omnibus Appropriations Act of 2009, Congress appropriated \$5 million to HHS to develop the Action Plan, with continued annual appropriations to support the coordination of the Action Plan, particularly by OPHS. Omnibus appropriations also continue to support the HAI-related work of the CDC (in epidemiological research, development of prevention guidelines, and data collection systems) and of AHRQ (in implementation research and dissemination of HAI prevention practices).

AHRQ, in particular, had initially funded much of its HAI-related research under general safety implementation initiatives, but has since received appropriations explicitly for projects to reduce and prevent HAIs, including \$5 million in FY 2008 for an initiative with CDC and CMS to identify gaps in the prevention, diagnosis, and treatment of MRSA-related infections, and \$17 million in FY 2009 for projects targeting a range of infections across a variety of ambulatory, acute, and long-term care settings.²²

Exhibit 11: Legislative and Regulatory Policy Related to Action Plan Activities

Legislative or Regulatory Policy	Primary HHS Agency Involved/Affected	Description
Omnibus budget appropriations process	OPHS/OHQ CDC CDC AHRQ	<ul style="list-style-type: none"> ▪ \$5m in FY 2009 to coordinate Action Plan (continuing) ▪ Continued appropriations for HAI epidemiological research, guideline development, and data collection systems ▪ FY 2009 mandate for States to develop HAI plans ▪ Continued funding for safety improvement research, including HAI-specific funding in FY 2008 (\$5m) and FY 2009 (\$17m)
American Reinvestment and Recovery Act (ARRA) of 2009	CMS CDC	<ul style="list-style-type: none"> ▪ \$10m (\$1m FY 2009, \$9m FY 2010) to improve ambulatory surgical center inspections ▪ \$40m to improve State HAI prevention capacity
Medicare Conditions of Practice (CoP)	CMS	<ul style="list-style-type: none"> ▪ Revised CoP interpretive guidelines for infection control in hospitals (2007) and in ambulatory surgical centers and long-term care facilities (2009)
Deficit Reduction Act of 2005	CMS	<ul style="list-style-type: none"> ▪ Inclusion of HAI-related hospital-acquired conditions (HAC) not to be reimbursed under Value-Based Purchasing incentives
QIO 9th Scope of Work	CMS	<ul style="list-style-type: none"> ▪ Inclusion of a safety improvement priority related to MRSA
Patient Safety and Quality Improvement Act of 2005	AHRQ	<ul style="list-style-type: none"> ▪ Collection, aggregation, and use of patient safety data (including HAI-related) by PSOs for quality and safety improvement
Healthy People 2010/2020	All agencies	<ul style="list-style-type: none"> ▪ Inclusion of HAIs in national disease prevention and health promotion objectives

The Omnibus Appropriations Act signed in March of 2009 also required States that receive Preventive Health and Health Services (PHHS) Block Grants to submit an HAI prevention plan to HHS by January 1, 2010. The legislation required the State plans to be consistent with the Federal Action Plan and specify measureable 5-year goals and interim milestones for HAI prevention. In its summary report to Congress in June 2010, HHS noted that, based on CDC's review, all States had submitted a plan that met the legislation's two broad requirements. Outside of the annual Omnibus appropriations process, the most significant source of funding for Action Plan activities has come from the American Reinvestment and Recovery Act (ARRA), passed in early 2009. Through ARRA, HHS received \$50 million for HAI-related priorities:²²

- \$10 million to CMS (\$1 million in FY 2009 and \$9 million in FY 2010) to improve the inspection process for ambulatory surgical centers and to develop, in collaboration with CDC, a new infection control survey instrument for these types of facilities; and
- \$40 million to CDC to aid States in creating or expanding State-based HAI prevention collaboration efforts, enhancing States' abilities to monitor and track HAIs, and building within State health departments a workforce trained in HAI prevention. Some of this funding to States is provided to enhance prevention collaboratives with existing AHRQ-funded projects.

A number of other specific legislative and regulatory changes have focused on HAI-related activities within CMS. Key CMS programs targeted by these policies include the Medicare Conditions of Participation (CoP) for hospitals, the emerging system for Value-Based Purchasing (VBP), and the Statement of Work (SOW) for Quality Improvement Organizations (QIOs), funded by CMS to assist Medicare-reimbursed health care organizations improve the quality and efficiency of their services.

- **Conditions of Participation (CoP).** To be eligible for payment under Medicare and Medicaid, health care providers must comply with HHS-established health and safety standards, known as conditions of participation. A CoP for infection control requires acute care hospitals to maintain an active infection control program with a designated person in charge.¹⁵
 - Many hospitals meet this requirement through accreditation by the Joint Commission, although certification by other bodies is also accepted.^{6, 15}
 - CMS also provides interpretive guidelines for the infection control CoP that reference best practice recommendations by expert organizations such as CDC, APIC, and SHEA.
 - In November 2007, the interpretive guidelines for the hospital infection control CoP were revised to reflect changing infectious disease threats as well as current nationally recognized guidelines, best practices, and other resources for hospitals.⁶
 - In 2009, similar revisions to the CoP interpretive guidelines for infection control were implemented for ambulatory surgical centers and long-term care facilities.⁶

- **Value-Based Purchasing (VBP).** CMS has pursued a number of demonstration projects and initiatives to incentivize improvement in health care services and transform Medicare from a “passive payer” to a more active purchaser of higher value health care services.^{6, 23}
 - A central initiative building on these experiences has been the Hospital-Acquired Conditions and Present on Admission Indicator Reporting program (HAC POA). The Deficit Reduction Act of 2005 required hospitals reimbursed through the Inpatient Prospective Payment System (IPPS) to submit data beginning October 2007 on whether specific diagnoses were present on admission (POA).
 - Effective October 2008, CMS stopped reimbursing such hospitals for a set of conditions acquired during hospitalization, termed “never events,” considered to be reasonably preventable errors in health care delivery.²⁴
 - The first set of hospital-acquired conditions (HACs) to fall under these rules included catheter-associated urinary and vascular infections, as well as several types of surgical site infections.
 - Proposed candidate HACs for future inclusion include two additional types of surgical site infections, ventilator-associated pneumonia, and *Clostridium difficile*-associated disease.²⁵
- **Quality Improvement Organizations (QIO).** Under Sections 1152–1154 of the Social Security Act, CMS contracts with one designated organization in each State and territory to improve the quality and efficiency of services delivered to Medicare beneficiaries. QIO contracts are 3 years in length, with each 3-year cycle referenced sequentially as a Statement of Work (SOW).^{11, 26}
 - One priority area of the current 9th Scope of Work (SOW) for QIOs is to improve the safety of care provided to Medicare beneficiaries.
 - The safety priority area has six components, one of which is to reduce rates of healthcare-associated methicillin-resistant *Staphylococcus aureus* (MRSA) infections in the acute care hospital setting.
 - The 9th Scope of Work also requires CMS and CDC to publicize, to hospitals reporting to the NHSN surveillance system, the opportunity to work with QIOs on MRSA-related prevention.
 - Two other specific legislative and regulatory programs that have focused on HAI-related activities are the recently created Patient Safety Organizations (PSOs) administered by AHRQ and the ongoing Healthy People initiative involving HHS agencies department-wide.
- **Patient Safety Organizations (PSOs).** In addition to QIOs, the Patient Safety and Quality Improvement Act of 2005 authorized the creation of Patient Safety Organizations (PSOs) to improve the quality and safety of health care delivery.²²

¹¹ <http://www.cms.gov/QualityImprovementOrgs/>

- By providing both privilege and confidentiality, PSOs are intended to create a secure environment where clinicians and health care organizations can collect and analyze data to identify and reduce risks and hazards associated with patient care.
 - HHS issued a final rule for PSOs in January 2009, which included the role of AHRQ in administering provisions governing PSO operations.
 - AHRQ has made available common definitions and reporting formats and has worked with CDC to ensure that the data collected by PSOs according to these “Common Formats” will be consistent with data reported to the NHSN surveillance system.
- **Healthy People Initiative.** Targets related to healthcare-associated infections have also been incorporated into HHS’ Healthy People initiative, a comprehensive set of disease prevention and health promotion objectives for the United States.²⁷
 - Although Healthy People is based on recommendations from a broad collaboration of scientists and stakeholders from within and outside government, its objectives have been specified by Congress as the measure for assessing progress of Federal programs such as those under the Indian Health Care Improvement Act and the Preventive Health and Health Services Block Grants.
 - It has also become a widely recognized basis for coordinated public health action on the national, State, and local levels.²⁷
 - Objectives for Healthy People 2010 included reduction of three types of hospital-acquired infections in intensive care unit patients (CAUTIs, CLABSIs, and VAP).²⁷
 - Proposed objectives for Healthy People 2020 include reduction of two types of HAIs (CLABSIs and MRSA).¹²

4.4.2 Policy Mandates and Expectations

In addition to the historical antecedents and legislative and regulatory actions reviewed above, a number of mandates and expectations have accrued for the Action Plan. Some of these resulted from direct legislative mandates—distinct from the legislation that funded HAI efforts and called for specific actions—others occurred as part of the policy development process. These mandates and expectations all contributed to the formation of the strategic environment within which the Action Plan operates and the basis on which it will be judged by those responsible for oversight and other interested stakeholders.

¹²<http://www.healthypeople.gov/hp2020/Objectives/TopicArea.aspx?id=26&TopicArea=Healthcare-Associated+Infections>

In **Exhibit 12**, we categorize these policy mandates and expectations according to the elements of the overall HAI prevention program system framework guiding the evaluation (see Exhibit 2 in Chapter 1).

Exhibit 12 : Policy Mandates and Expectations for the Action Plan

Policy Mandates and Expectations	Element of HAI Prevention System Framework
Reduction of duplicative efforts and increased cohesion of HAI activities among agencies within HHS One of the main implications of the March 2008 GAO report and the subsequent Congressional hearings on HHS' HAI prevention efforts. It specifically relates to leadership and strategy within HHS.	Leadership and Strategy
Alignment and coordination of HAI prevention efforts and resources across Federal, State, and local levels Alluded to briefly in comments in GAO report, more visible during the Congressional hearings, and a specific focus of the Omnibus Appropriations Act of 2009 mandating States to develop HAI plans. This expectation relates to leadership and strategy, as well as coordination of action to implement prevention practices down to the local point of care.	Leadership and Strategy HAI Prevention Practice Adoption
Standardization and interoperability of HHS data systems for surveillance and reporting of HAI incidence One of the GAO report's two main recommendations. These relate to both the integration of data systems and outcomes monitoring components within the HAI Prevention system framework.	HAI Data and Monitoring
Prioritization of HAI prevention practices The second main recommendation in the GAO report. This expectation relates to the research and evidence needed to prioritize practices, as well as to other criteria such as the feasibility and affordability of implementing specific prevention practices.	Knowledge Development HAI Prevention Practice Adoption
Expansion of scope from acute care hospitals to other health care settings, including ambulatory and long-term care facilities This point is recognized in currently funded HAI activities of HHS agencies that address HAIs in non-hospital settings and in the proposed areas for future expansion in the Action Plan itself.	HAI Prevention Practice Adoption
Substantial reductions in rates of targeted HAIs over time Although specific targets for HAI reduction are not part of the legislation, implicit in Congressional attention to HAIs and the funding of the Action Plan and its related components is a strong expectation that HHS will make substantial progress on its self-defined 5-year targets to reduce national rates for particular HAIs. Although making progress on these targets will also require progress on the other elements of the HAI Prevention system framework, it is likely that this expectation will represent the main criterion on which the Action Plan is judged.	Effects on Stakeholders

5. INPUT EVALUATION RESULTS

In this chapter we report the results of the Input evaluation of the Action Plan. As discussed in Chapter 1, the objective of the Input evaluation was to identify the program strategies and their relative strengths and limitations for achieving the Action Plan. While the Context evaluation examined decisions that were considered with respect to the expectations of the Action Plan, our Input evaluation focused on the strategic and resource inputs for accomplishing those goals. The Input evaluation conducted by the IMPAQ/RAND team in Year 1 of this project specifically sought to:

- Identify the resources available for performance of the Action Plan;
- Identify the key organizations involved in developing the Action Plan;
- Capture the interactions between the key organizations and the coordination of their roles and responsibilities;
- Identify the various stakeholders of the Action Plan and their interactions with the Action Plan's lead organizations;
- Identify the criteria used to compare potential programs resulting from the Action Plan against each other and in relation to existing programs; and
- Describe the programs that were planned for or subsumed under the Action Plan initiative.

The chapter is organized according to key themes related to the development of the Action Plan, the organization of the Action Plan and the initial roles and activities of key agencies and stakeholders, perceived strengths and limitations of Action Plan strategy and structure as reported by interview participants, and a summary of Input evaluation findings in relation to the HAI prevention system framework introduced in Chapter 1.

5.1 Overview of Key Findings

- Many interviewees expressed the view that development of the Action Plan was relatively rushed, and believed HHS should have been given more time to complete the task. Some thought the Plan might have been organized differently if more time had been available, while others felt that the tight timeline created a missed opportunity for publicizing the Action Plan to the general public.
- There was strong consensus among interviewees that the main contributors to the development of the Action Plan were representatives from AHRQ, CDC, and CMS, with a strong coordinating role played by OPHS.
- Stakeholders identified a number of strengths in the Action Plan, including the promise of stronger coordination of HAI activities across HHS; the targeting of priority HAIs and organism-specific agents for acute care in the hospital setting; the increased visibility

and accountability for HAI issues created by the plan; and the accelerated pace of HAI prevention and reduction activities.

- Some limitations in the plan were also noted by interviewees. These included the Plan's lack of operational guidance on how to implement the plan; a sense among about half of interviewees that the plan's HAI prevention targets might be unrealistically difficult to attain in the given time frame; concerns that metrics were epidemiologically derived and therefore not appropriate for population-based measurements; and the plan's insufficient concern with stakeholder engagement.

5.2 HHS Action Plan Development

5.2.1 Development of Work Tasks and Responsibilities

As discussed in Chapter 2, following the release of the March 2008 GAO report and the subsequent Congressional Hearings in April 2008, the Deputy Secretary of HHS tasked the OPHS to convene an interagency Steering Committee to develop and implement the Action Plan. The Steering Committee was formed in the summer of 2008. Composed of senior-level representatives from HHS Offices and Operating Divisions, the Steering Committee is chaired by the Deputy Assistant Secretary for Healthcare Quality, and staffed by the Office of Healthcare Quality (OHQ). The Steering Committee brought together prominent clinicians, scientists and other public health professionals from across HHS agencies to develop the Action Plan.²⁸

The stated purpose of the Action Plan is to establish national prevention goals and outline specific actions that enhance the ability of HHS to coordinate the prevention efforts of its various operating divisions.⁶ To accomplish these goals, the Steering Committee formed a working group structure, which initially involved five working groups:

- **Prevention and Implementation Working Group** – tasked with prioritizing, in partnership with HHS' Healthcare Infection Control Practices Advisory Committee (HICPAC), existing recommended clinical practices to facilitate implementation in health care organizations.
- **Research Working Group** – charged with identifying gaps in the existing knowledge base of current infection control practices and developing a coordinated research agenda to strengthen the science for infection control prevention in hospitals.
- **Information Systems and Technology Working Group** – responsible for establishing a plan for the standardization of HAI measures and alignment of data definitions needed to measure HAIs and enhance interoperability of data systems across HHS agencies.
- **Incentives and Oversight Working Group** – tasked with exploring opportunities for evaluating compliance with infection control practices in hospitals through required certification processes and identifying additional options for the use of payment policies and financial incentives to motivate organizations to provide better, more efficient care.

- **Outreach and Messaging Working Group** – charged with developing a plan for national messaging regarding HAI prevention to raise awareness among various stakeholder groups across the United States, with a special emphasis on consumer education and activation.

Early in the development of the Action Plan, the Steering Committee decided to focus on HAIs in acute care settings. The working groups, therefore, initially focused on hospital-based acute care settings, which the Action Plan terms Tier 1 activities. As described in Chapter 2 and discussed later in this chapter, activities in the first year of Action Plan implementation targeted four infection categories—SSIs, CLABSI, VAP, and CAUTI—and two organism-specific infections—*Clostridium difficile* and MRSA. Over the course of the first year, two additional working groups were added to the Action Plan:

- **Evaluation Working Group** – responsible, in partnership with external stakeholders, for developing the metrics and targets associated with the initiative. It is also responsible for developing and refining a framework for evaluating HHS’ activities related to the Action Plan.²⁹
- **Healthcare Workers Influenza Vaccination Working Group** – focused on developing a list of benchmarks for measuring short-term, mid-term and long-term progress objectives for influenza vaccination of health care workers within the United States, which will be aligned with the Healthy People 2020 objectives.²⁹

During the first year of operation of the Action Plan, the Steering Committee also initiated two Tier 2 working groups focused on HAI prevention in other acute health care settings: ambulatory surgical centers and hemodialysis centers. Proposed Action Plan modules for the Healthcare Workers Vaccination, ambulatory surgical centers, and hemodialysis centers working groups were drafted in August 2010, with planned feedback from stakeholders expected at the “Progress Toward Eliminating Healthcare-Associated Infections” meeting in late September 2010, before being submitted together for HHS clearance and final inclusion in the Action Plan.

5.2.2 Stakeholder Feedback Provided to HHS During the Development of the Action Plan

The selection of priority measures and 5-year national prevention targets was led by CDC and accomplished with the help of individuals who attended a stakeholder meeting in September 2008. The meeting convened key stakeholders from research institutions, Federal and State government, and consumer groups. The selection of targets was coordinated with the measures used within Healthy People 2020, another HHS initiative.

The draft Action Plan was released in January 2009. After its initial release, a public comment period lasted through early February 2009. General comments about the Action Plan included the following:

- Encouragement to expand the Action Plan beyond acute care hospitals to include long-term care facilities and ambulatory surgical centers;

- A request for a call for mandates and actionable items; and
- The need to include education of students and health care professionals as part of any effective outreach and implementation efforts.

Comments directed to the Prevention and Implementation Working Group included an increased emphasis on hand hygiene and a concern about how local implementation of the Action Plan would work. The Research Working Group received recommendations to focus on determining which infections are preventable and how patient factors influence HAI incidences. This group also received recommendations to include implementation research as a key component of the research agenda.

Comments directed to the Information Systems and Technology Working Group included recognition of the importance of utilizing the National Healthcare Safety Network (NHSN), CDC's main surveillance system of HAI rates in hospitals, as a data collection framework as well as concerns about linking local hospitals to regional and national IT networks.

Comments for the Incentives and Oversight Working Group emphasized that determination of the validity of metrics and measures was extremely important so that metrics could be credibly linked to the payment processes. This group was also encouraged to consider the possibility of unintended consequences of mandatory reporting.

Comments directed to the Outreach and Messaging Working Group included stressing the importance of having education and patient involvement as key themes within their work. The comments were taken into account by HHS and a revised version of the Action Plan was released in June 2009.³⁰

Recognizing the importance of ensuring input and reactions from professional and public stakeholders not directly involved in the development of the Action Plan, HHS also held a series of public meetings throughout the summer and fall of 2009. Four meetings were designed to gather feedback on the Action Plan in general, while three meetings were focused specifically on IT issues. The general Action Plan meetings employed different recruitment targets. The Washington, DC meetings sought participants primarily from national organizations. The Denver, Chicago, and Seattle meetings were intended to have more regional and local representation. Additionally, the Chicago and Seattle meetings had a higher representation of health care professionals and institutions, while the Denver meeting included a greater number of health care consumers (i.e., the general public). During the meetings, stakeholders' input was sought regarding the barriers, needs, and solutions impacting implementation of the Action Plan. The HHS report summarizing these stakeholder meetings categorized the needs expressed by participants into the following themes:

- Accountability and cultural change;
- Data and reporting systems;
- Alignment of priorities, systems, and roles;

- Education and outreach for health care personnel and patients; and
- Resources.

During the IT stakeholder meetings, a wide variety of needs and barriers were discussed. Examples include the need for greater financial resources, building capacity and expanding IT training opportunities, and improved interoperability between data systems. The stakeholders went so far as recommending a mandate that a single HAI data collection be used, and suggesting that NHSN might be that system if its usability could be improved.³¹

5.2.3 Findings on the Development of the Action Plan from the Key Stakeholder Interviews

We asked interviewees what they thought about the process that was followed to develop the Action Plan. We asked how effectively the process worked, who the involved stakeholders were, and whether they were the right mix of participants.

- Several interviewees reported that the process of developing the Action Plan was relatively rushed. HHS was given only several months to complete the plan, a brief window given the amount of time usually provided for an endeavor of this breadth and magnitude.
- While some people viewed “forcing HHS to produce something expediently” as a benefit to the tight timeline, other interviewees reported that the plan might have been organized differently if more time had been available to produce it.
- However, a few from this latter group of interviewees were less concerned about the speed of the process because they considered the Action Plan a “starting point” for better coordination of HHS’ HAI prevention efforts.
- Others commented that the tight timeline created a missed opportunity for publicizing the Action Plan to the general public. Some external stakeholders we spoke to encouraged HHS to put more effort into publicizing the initiative.
- Several interviewees gave credit to HHS for the fact that the Action Plan “survived” a new presidential administration.

There was also general agreement that the individuals who contributed to various sections of the Action Plan were among the top experts in their areas. Thus, despite the pace of creating the Action Plan, “it was not lacking for scientific rigor.”

- There was strong consensus among Federal agency interviewees that the main contributors of content to the initial Action Plan document were representatives from AHRQ, CDC, and CMS, with a strong coordinating role performed by OPHS.
- The other signatory agencies to the Action Plan—ASPA, ASPE, FDA, NIH, and ONC—as well as two other HHS agencies—the Health Resources and Services Administration (HRSA) and the Indian Health Service (IHS)—were recognized as contributing specific expertise and agency comment to the development of the Action Plan.

- Individuals from outside HHS (e.g., researchers, infection control specialists, clinicians, consumer advocates) contributed advice to the Steering Committee and working groups either formally or informally, and/or provided feedback via the HHS stakeholder meetings described above.

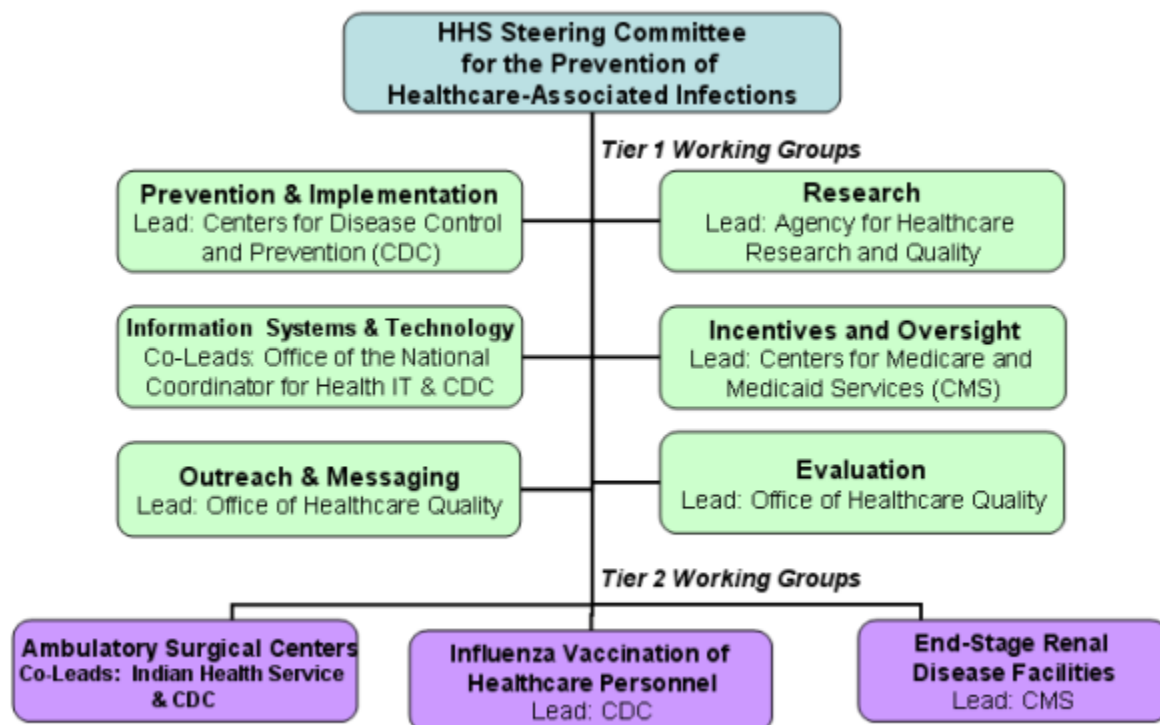
5.3 Overview of Action Plan Organization, Roles, and Activities

5.3.1 Action Plan Organization and Initial Inputs

One of the fundamental inputs relates to how the process of the Action Plan was developed. While this is addressed with the Context Evaluation, it is also relevant to the Input Evaluation since the Evaluation assesses the Plan for coordination among stakeholders and inclusion of stakeholder viewpoints.

Exhibit 13 displays the organization of the Steering Committee and working group structure described above and indicates the lead agencies for each of the Tier 1 and Tier 2 working groups.

Exhibit 13: Organizational Structure of the HHS Initiative for the Prevention of Healthcare-Associated Infections



Source: Office of Public Health and Science.²⁹

In addition to taking a key role in the development of the Action Plan, AHRQ, CDC, CMS, and OPHS were considered by internal and external stakeholders to be the core agencies leading the implementation of the Action Plan. The five other signatory agencies to the Action Plan (ASPA, ASPE, FDA, NIH, and ONC) and two other HHS agencies involved in the development of the Action Plan (HRSA and IHS) also have representatives that serve on the HHS Steering Committee and play various roles in the working groups.

Since the release of the Action Plan, the Veterans Health Administration (VHA) has joined the Steering Committee and working groups and represents the only non-HHS agency directly participating in the Action Plan initiative.

Below, we identify initial inputs and activities related to the Action Plan from the four main lead agencies, other Federal agencies, and key stakeholder groups that contributed to Action Plan activities.

AHRQ Initial Inputs and Activities. As the Federal agency focused on health quality research, AHRQ's role in the Action Plan initiative is to provide a synthesis of effective strategies for preventing HAIs and the dissemination and implementation of prevention practices. Its portfolio of health services research encompasses all six priority HAIs included in Tier 1 of the Action Plan, as well as other infections (e.g., KPC or Carbapenem-resistant Enterobacteriaceae) and other health care settings (e.g., hemodialysis centers). As described in Chapter 4, AHRQ also has responsibility for administering the recently authorized Patient Safety Organizations (PSOs) that will enable clinicians and health care organizations to more readily collect and analyze data to identify and reduce risks associated with patient care, including HAIs.

AHRQ is the lead agency for the Research Working Group and also has representatives who serve on the Prevention and Implementation, Information Systems and Technology, Incentives and Oversight, Outreach and Messaging, and Evaluation Working Groups.

CDC Initial Inputs and Activities. The CDC's position, at the helm of the network of State health departments, affords it a means to translate Federal action to the local level. Through its data collection systems (most notably NHSN) and its long history of research into HAI prevention, CDC provides the data for metrics of improvement in HAI prevention, as well as the framework for HAI data surveillance. The CDC network, including a Federal agency, 10 CDC regions, and 50 State health departments, also serves as a ready-made conduit for the dissemination of prevention strategies and support for implementation. As described in Chapter 4, CDC received substantial funding through the American Reinvestment and Recovery Act (ARRA) of 2009 to expand State-based HAI prevention collaboration efforts, States' capacities to monitor and track HAIs, and the workforce trained in HAI prevention in State health departments.

CDC is the lead agency for the Prevention and Implementation and the Influenza Vaccination of Healthcare Personnel Working Group Working Groups, as well as a co-lead agency for the Information Systems and Technology and the Ambulatory Surgical Centers Working Groups.

CDC representatives also serve on the Research, Incentives and Oversight, and Outreach and Messaging, and Evaluation Working Groups.²⁹

CMS Initial Inputs and Activities. Under the Action Plan, CMS has a range of activities related to HAI as part of the Evaluation of the Hospital-Acquired Conditions Present on Admissions (HAC POA) Indicator Reporting Program, which measures the impact of HAC POA on the incidence of selected conditions; effects on Medicare payments, utilization, quality and patient safety; impacts on coding accuracy; unintended consequences; and infection and event rates. CMS is also carrying out two HAI-related projects through its Quality Improvement Organization (QIO) network: a CAUTI project, which will introduce evidence-based prevention processes to targeted hospital systems; and a *Clostridium difficile* infection project, which seeks to achieve a case-rate reduction of *C. difficile* infections by 30 percent through the adoption and implementation of prevention processes in the hospital setting. CMS, in its role as payer for Medicare and Medicaid patients, exerts the “power of the purse” in its quality improvement projects, and can incentivize HAI prevention practices as part of its goal of quality improvement. As described in Chapter 4, CMS also received ARRA funding to improve the inspection process for ambulatory surgical centers and to develop, in collaboration with CDC, a new infection control survey instrument for these types of facilities.

CMS is the lead agency for the Incentives and Oversight and the Hemodialysis Centers Working Groups. The agency also has representatives who serve on the Prevention and Implementation, Research, Information Systems and Technology, and Outreach and Messaging Working Groups.

OPHS Initial Inputs and Activities. In its role as the coordinating agency for the Action Plan, OPHS’ Office of Healthcare Quality (OHQ) is responsible for ensuring that the HAI prevention activities of the Federal agencies are translated into changes at the State and local levels, and that the Action Plan is properly evaluated to enable it to achieve maximal impact. In addition to chairing and providing staff support to the Steering Committee, OHQ has direct responsibility for several HAI projects and programs, including the National Media Campaign to Prevent Healthcare-Associated Infections, which is intended to promote the patient-provider relationship in preventing HAIs, and the development of computer-based HAI prevention training to be offered free of charge to clinicians and health professions students. OPHS has also funded a series of HAI prevention projects proposed by HHS Regional Health Administrator offices to address key HAI activity areas (capacity building, reporting, prevention, evaluation, and communication).¹³ OPHS is the lead agency for two working groups: Outreach and Messaging, and Evaluation.

Other Federal Agencies’ Initial Inputs and Activities. A number of Federal agency stakeholders specifically identified the participation of the full range of HHS agencies and VHA in the Action Plan as providing complementary assets and considered it essential to the plan’s success. Interviewees described the particular inputs offered by these agencies:

¹³ See http://www.hhs.gov/ophs/initiatives/hai/statelevel/state_level_act.html.

- **ASPA** – expertise in communication and messaging to a variety of public health and health care audiences, including providers, institutions, and consumers.
- **ONC** – a critical player in national health information technology policy, with expertise applicable to several key areas of the Action Plan, including improving the interoperability of large health information databases, reducing user burden for data collections systems, and integrating electronic health record (EHR) and regional health exchange data systems with HAI surveillance systems.
- **FDA** – expertise with the medical equipment industry and the design of medical devices, an increasingly recognized source of HAIs and a potential emerging priority for the Action Plan.
- **HRSA and IHS** – expertise in the provision of health care services to consumers (in contrast to other HHS agencies), with particular emphasis on ambulatory care, which will be the focus in Tier 2 of the Action Plan.
- **VHA** – expertise in the provision of health care services in a wide variety of settings, from inpatient to ambulatory and long-term care facilities. VHA is also a nationally recognized leader in patient safety improvement, with specific HAI-related initiatives.

External Stakeholders’ Initial Inputs and Activities. As discussed in Chapter 4, the GAO reports on HAIs highlighted the role of accreditation and survey bodies, such as the Joint Commission, in requiring health care delivery organizations to implement HAI prevention policies and practices.¹⁵ Our sampling of stakeholders identified a wide range of non-Federal stakeholders in HAI prevention, including health care providers and professional associations, industry and trade associations, purchasers and insurers, accreditation and standards-development organizations, health care improvement organizations, consumer and patient advocacy groups, and academic and research institutions (see Chapter 3).

Our interviews with representatives from these stakeholder groups emphasized, as detailed in Chapter 4, that many of these stakeholders have been involved in addressing HAIs for years or even decades prior to development of the Action Plan. They possess extensive expertise and resources in HAI prevention, such as experience with development of professional guidelines and evidence-based practices, dissemination and implementation strategies, and design of incentive systems. As one external stakeholder stated, “these activities [have been] happening regardless of the Action Plan.”

At the same time, external stakeholders indicated the complementarities of their activities with the work of the Action Plan. For example, one interviewee noted that “one of the things the Action Plan ... is branching out into [is] ambulatory surgical centers and outpatient care, and that’s ... what we’re doing here.” Another similarly commented, “We’re actively involved in implementation of state laws, and that often bleeds over into state action plans.” In addition, a number of stakeholder organizations have long-standing relationships working with individual HHS agencies on patient safety, quality, and HAI issues in particular, such as AHRQ’s initial projects on MRSA and SSIs.

These interviews underscored a variety of inputs that external stakeholder groups offer or have already contributed to the Action Plan:

- **Healthcare provider and professional associations** – development of practice guidelines, professional influence on provider behavior, advocacy for changes in health care policy.
- **Industry and trade associations** – capacity to mobilize member organizations, advocacy of specific policies, dissemination of organizational practices.
- **Purchasers and insurers** – power of the purse related to financial incentives, administrative data, support for quality and safety improvement.
- **Accreditation and standards-development organizations** – “soft regulation” in the form of voluntary standards, mandates related to certification requirements.
- **Health care improvement organizations** – dissemination and implementation of prevention and improvement practices, mobilization and advocacy for health care policy change.
- **Consumer and patient advocacy organizations** – consumer education, particularly related to interactions with health care providers, attention to self-care, and choice of medical providers, as well as advocacy for policy change, with particular emphasis on public reporting to support consumer choice. Consumer and other stakeholder interviewees also believed that, despite the varied roles consumers can play, ultimate responsibility for HAI prevention rests with health care systems and providers.
- **Academic and research institutions** – development of knowledge on HAIs, translation of research into evidence-based prevention practices, evidence on effective dissemination and system change strategies.

5.3.2 Working Group Operations

We asked the interviewees associated with Action Plan agencies about their involvement in the working groups. We interviewed at least one agency member from each of the working groups, except the two related to Tier 2.

- Overall, the respondents reported positive experiences with the working groups, although a few expressed concerns over the amount of effort expended versus the amount or pace of progress.
 - Most agreed that the working groups brought different agencies together, working toward a common goal while not overlapping efforts.
 - Each working group has individuals from various agencies represented. “We cross over so many workgroups.”
 - Many participants are pleased with the level of interagency interaction.

- Most considered the goals and activities of the working groups in which they are involved to be aligned with the objectives and responsibilities of the working groups as defined in the Action Plan.
- Some interviewees expressed concerns related to the operation of the working groups:
 - A small number were concerned with the efficiency of the working groups. For example, one interviewee reported, “We question how efficient and productive they are.... The amount of investment would be measured in hundreds of hours.”
 - A few were similarly concerned about the strain on their agency’s resources, given the time and personnel resources required of the working group and steering committee meetings, both in person and during conference calls, with some wondering whether they “have been more work than benefit.”
 - Several participants commented that the Tier 1 working groups appeared to have become less active after the completion of the initial Action Plan document.

5.4 Strengths of the Action Plan As Reported By Interview Participants

As part of our interviews, the IMPAQ/RAND team asked both external and internal stakeholders to comment on what they considered the primary strengths and potential limitations of the Action Plan. The focus here was on higher level, strategic considerations related to the initial decisions on how to organize and implement the Action Plan and its ensuing activities. We address in this section the perceived strengths of the Action Plan, and, in section 5.5, the perceived limitations.

5.4.1 Promise of Coordination of HAI Activities across HHS Agencies

When asked about the strengths of the Action Plan, rather than pointing to any specific aspect or strategy, the most common response from interview respondents was that the Action Plan holds promise for better coordination across HHS agencies with respect to their HAI activities and strategies. This view was particularly expressed by respondents from the Federal agencies who were signatories to the Action Plan. Indeed, they reported improved coordination consistent with the recommendations of the 2008 GAO report that catalyzed the development of the Action Plan.¹

- Respondents pointed to several potential benefits of this improved coordination, including the possibility for synergies across agencies, a reduction in duplicative efforts, improved capacity to leverage the strengths of each agency, identification of the agency best suited for each project component, and the use of collaborative interagency agreements.

- While acknowledging that the Action Plan's implementation is still at an early stage, with much more work remaining to fully coordinate efforts, representatives from the Federal agencies consistently reported improved working relationships.
- They also described an emerging new trust among agencies since the Action Plan's development, even though operational coordination remained nascent. A number of Federal agency participants perceived that turf issues among agencies have been kept to a minimum, as participants emphasized the unique assets and complementarities of agencies.

There are several instances of this coordination to date:

- For example, the Steering Committee created the Influenza Vaccination of Healthcare Personnel Working Group Working Group in September 2009. When it was subsequently discovered that a similar work group existed within HHS's National Vaccine Program Office, the two groups merged rather than continue redundant efforts.³²
- CDC and CMS decided jointly that NHSN would be the tool that facilities will use to participate in the CMS HAI pay-for-reporting program and reported on Hospital Compare starting in 2011.¹⁴
- The Evaluation Working Group has discussed coordinating with the Federal Interagency Workgroup for the Healthy People 2020 initiative to tie its HAI-related goals to the Action Plan goals.
- Interagency collaboration is also evidenced in initiatives such as AHRQ, CDC, CMS, and OPHS working collaboratively to implement the outreach and messaging campaign headed by the Outreach and Messaging Working Group.
- AHRQ, CDC, CMS, and ONC are developing a proposal in the Information Systems and Technology Working Group to integrate HAI data collection across systems, automate data collection from electronic health records, and increase the interoperability of systems.³³

A number of interview respondents identified the role of the Deputy Assistant Secretary for Healthcare Quality (OHQ) and the chair of the Steering Committee, and the Office of Healthcare Quality as especially important for ensuring ongoing and continued cooperation. Several Federal agency interviewees noted the continual effort that it takes to keep agencies focused on Action Plan activities and motivated to work together. Respondents noted that it is critical to have a visible and effective individual who ensures the overall coordination of the Action Plan. Several stakeholders from within HHS agencies also indicated the potential of the Action Plan as a model and potential infrastructure for interagency coordination of the other health care quality priorities within the department. Previous attempts at interagency coordination within HHS on quality and safety issues, such as the Quality Interagency Coordination (QuIC) Task Force and a Patient Safety Task Force, were described in the interviews as relatively short-lived.

¹⁴ <http://www.cdc.gov/nhsn/cms-welcome.html>, downloaded August 2010

As the Action Plan has advanced, several interviewees mentioned growing interest and expectations within HHS for applying the Action Plan’s “coordinated approach” to other health care quality concerns.

5.4.2 Selection of Infections for the Action Plan to Address

The Action Plan’s final draft addresses six “high-priority HAI-related areas” in the acute care hospital setting. These included four categories of infections (SSIs, CLABSI, VAP, and CAUTI) and two organism-specific priorities considered to be emerging HAI issues (*Clostridium difficile* and MRSA).⁶ The IMPAQ/RAND team queried interviewees about whether they considered the HAIs selected in the Action Plan to be the “correct” or “appropriate” infections to be targeted for action. They were also asked whether different infections should have been selected, and whether some selected infections should have been omitted.

In general, the types of infections selected were considered strengths of the Action Plan. The large majority of respondents from both Action Plan agencies and external stakeholders believed that the selected infections were appropriate. Most expressed an appreciation that it was necessary to prioritize among the possible HAIs. The infections selected are among the most prevalent, deadly, and costly,^{34, 35} which respondents considered reasonable criteria for selecting infections to include in the Action Plan. Moreover, respondents noted that expert input was taken into account in the selection of these infections, which lent added credibility to their inclusion.

The external and internal stakeholders we interviewed therefore recognized the HAIs selected for the Action Plan as an appropriate set to highlight as priorities for HHS and the health care community.

Despite the general agreement with the selected set of HAIs, there was a minority viewpoint—expressed by both Federal agency representatives and external stakeholders—that the Action Plan should not have separated out the microorganism-specific infections (*Clostridium difficile* and MRSA). In initial drafts of the Action Plan, MRSA in particular was not singled out as a separate HAI but rather addressed as a causative organism of other types of HAIs.³⁶ The Action Plan still considers MRSA as such, but in order to address emerging HAI concerns, the Steering Committee subsequently decided to include MRSA and *C. difficile* as organism-specific priorities. One apprehension about including them as priorities was that they introduced a lack of consistency by focusing on pathogens as compared with clinical conditions, which are the focus of the other four identified priority HAIs. Comments on the Action Plan submitted by two epidemiological and infectious disease professional societies—SHEA and IDSA—also express concern that “concentration on a single organism, like MRSA, may divert attention from other locally prevalent organisms.” For example, MRSA is not unique as a resistant organism. Vancomycin-resistant enterococcus, extended beta-lactamase gram negative organisms, and KPC resistant *Klebsiella* organisms are examples of additional resistant bacteria not selected. On the other hand, rationale for including *C. difficile* as an organism-specific priority is

supported in part by its being nearly unique in not being killed by the alcohol gels that people use as a substitute for hand washing, reflecting the robust nature of the organism's spores.

A few respondents indicated drawbacks associated with including ventilator-associated pneumonia (VAP). They expressed the opinion that it might have been better to delay incorporating it as a major focus of the Action Plan until a feasible definition of VAP had been agreed upon. However, most felt it was appropriate to include VAP as a condition for study while withholding specific metrics until resolution of the definition was pursued. The notion of withholding metrics on this HAI in the initial version of the Action Plan was supported, for example, by the February 2009 SHEA/IDSA comments on the Action Plan, which agreed with HHS on withholding a specific target, because no valid outcome or process metric for VAP had yet been identified.

To address this issue, CDC is partnering with OHQ to convene pulmonary, critical care, hospital epidemiology and infection control, and infectious diseases experts to discuss the topic "Refining Surveillance Definitions for Ventilator-Associated Lower Respiratory Infections" in September 2010.³⁷

This activity reflects the adaptation and flexibility that the Steering Committee has attempted to infuse into the Action Plan to respond to changing HAI circumstances and priorities. A number of Federal agency interviewees reiterated the intent of the Action Plan to be a "living document," with HHS promising to update it at least every two years, a process that OPHS plans to start with a meeting of experts and stakeholders to reflect on "Progress Toward Eliminating Healthcare-Associated Infections," also planned for September of 2010. One Federal agency stakeholder even thought "it would be helpful to revisit the priorities, metrics, and the measurement/collection systems on an annual basis."

5.4.3 Visibility and Accountability for HAI Issues

Several interview participants felt that a strength of the Action Plan was that simply having such a plan brings increased attention and focus to a critical issue. For example, participants expressed comments such as, "just the fact that the Action Plan was created is a strength" because it acknowledges the importance of HAI and demonstrates a commitment by HHS to the issue. As a corollary, several participants reported that Congressional funding for the Action Plan was a strength, because it demonstrated support for HAI efforts and encouragement of the Action Plan as a means to address these issues. Others, particularly external stakeholders, reported that the Action Plan was important to securing additional funding for HAI initiatives, such as the Preventive Health and Health Services Block Grants included in the ARRA funds that were distributed to States. The availability of these funds both spurred States to create plans that were coordinated with the Action Plan, and also provided funds for important projects such as infrastructure creation and the expansion of the NHSN surveillance system. In fact, as noted in an OPHS Web conference held on August 19, 2009, to receive the full allotment of the ARRA funds, plans submitted by the States were required to be consistent with the Action Plan. Interview participants from Federal agencies indicated that the Action Plan created a structure that made agencies more accountable for working together. The fact that working groups exist

and report to the Steering Committee whose leader is housed in the Office of the Secretary creates a level of accountability for collaboration that may not have existed before the Action Plan. For example, one participant from a Federal agency stated that “OPHS’s involvement has strengthened our efforts. We were working with the goodwill of everyone before [to promote collaboration]. Now there’s more money, attention from the top, and assistance from the Secretary. That level of focus and commitment has been very important.”

5.4.4 Increased Speed of HAI Activities

Many of the Federal agency representatives interviewed indicated that while their particular strategies for addressing HAIs may not have changed, the Action Plan catalyzed the speed of these efforts and coordination with other agencies. One participant described the change as “like a garden hose before, and like a fire hose now.” Many participants noted that their involvement in the Action Plan had created networking opportunities with other agencies and helped solidify partnerships. This increased collaboration was called a “strong positive effect of the Action Plan.” Some noted that the Action Plan provided a “structure and guidance for activities that might not have taken place without the plan.” Several participants agreed that the Action Plan has encouraged coordination across agencies to align processes. For example, research to be conducted is presented to the Steering Committee to ensure that it aligns with the priorities of the working groups, thus optimizing complementary rather than duplicative efforts.

External stakeholders likewise generally felt that the Action Plan activities coincided with their work on HAI and brought attention to those areas. However, external stakeholders consistently reported that the Action Plan had not yet substantively changed their activities or strategies. Overall, stakeholders suggested the spread of HAI activities increased as a result of enhanced funding and coordination of mission and efforts.

5.5 Limitations of Action Plan As Reported By Interview Participants

Although a number of strengths of the Action Plan emerged from the interviews, notable limitations were also identified.

5.5.1 Lack of Operational Specification

The most frequently mentioned limitation of the Action Plan, cited by both Federal agencies and external stakeholders, was a lack of clear operational guidance on how to implement the plan and create change. In general, most viewed the Action Plan as a high-level document. They saw it as expressing a vision for HHS and the broader health care community’s efforts for reducing HAIs, and documenting current activities related to HAI. However, many respondents indicated that there is a need in the Action Plan for clear operational guidance on how to implement the Action Plan, create change, and reach the targets established in the plan. For example, one respondent noted, “the big challenge now is [there is] not enough attention on the implementation approach.”

The summary of public comments received by HHS about the Action Plan also noted a desire for actionable items and specificity about implementation.⁶ The SHEA/IDSA response to the Action Plan reflects this perception; for example, “an Action Plan should contain well defined action items, with defined deliverables that are designed to achieve objective goals within a specified timeframe ... included is a set of metrics with associated targets, but no clear roadmap for each agency as to how specific targets are to be achieved,” and “alignment among agencies is referenced ... however it is not clear as to how this will be achieved.” Comments submitted by a number of consumer groups also indicated a preference for further operational specificity. These groups consistently criticized the Action Plan for a lack of specific requirements and mandates.³⁸

The desire for increased specificity has been acknowledged by the Steering Committee. Some committee members have expressed a desire that in the next iteration of the Action Plan, each chapter should specify what the working groups are doing to reach the prevention targets.³⁹ Efforts have begun to consider how to revise the Action Plan to add increased clarity and specificity.³⁶ For example, the Steering Committee has formulated options for a revised Action Plan that might include an Executive Summary highlighting the strategic aspects of the overall Action Plan, plus specific modules focused on types of health care facilities (e.g., acute care hospitals, ambulatory surgical centers, hemodialysis centers) that would include operational tasks specific to those settings.

5.5.2 Setting of HAI Prevention Targets

A critical, high-level strategic input into the Action Plan was the development of national 5-year prevention targets with specific metrics to assess progress toward reduction of the HAIs addressed by the Action Plan. These metrics establish process and outcome measures for specific reduction targets for five of the six HAIs in the plan. (As noted above, no valid process or outcome metric has been identified for VAP, and the Action Plan therefore does not yet include a metric for this HAI.)

The IMPAQ/RAND team sought to assess whether the prevention targets in the Action Plan were considered appropriate and realistic. We therefore included questions in the interview protocols to assess the perceptions of these targets. In general, views on the prevention targets were decidedly mixed.

- About half the respondents we interviewed indicated that the prevention targets were appropriate, and the other half suggested that they were potentially difficult, if not infeasible to achieve, given the scope and complexity of the issues; the difficulty in measurement; limitations in the evidence base, resources and infrastructure required; and the limitations of the Federal role in addressing HAIs. (The idea that goals will be difficult to reach is supported by a report on the stakeholder meetings from September 2009. The report describes the polling of participants in a Washington, DC stakeholder meeting, in which 91 percent of attendees indicated that the 5-year reduction targets were moderately difficult or difficult to reach.³¹)

- Among the interview participants, there were two divergent views on the setting of these difficult targets.
 - One perspective was that these goals are appropriate as stretch or aspirational targets to motivate action and drive concerted efforts to reduce HAIs. This perspective generally suggests that even if the targets are not fully achieved, considerable progress will have been made trying to reach them.
 - Another perspective viewed the goals as potentially unrealistic, with concerns expressed that *not* reaching these difficult targets might result in efforts being viewed as unsuccessful, even if good progress were made.
 - A few respondents also questioned whether the targets were sufficiently evidence-based and emphasized benchmarking of rates as a high priority to set better goals.
 - There was concern that the targets might not be sufficiently adjusted over time as new evidence comes in regarding the feasibility of reaching them.
- A small minority suggested that the prevention targets were actually not set high enough. This view is captured in comments submitted jointly by eight consumer groups on February 6, 2009, which expressed concern that several of the goals were too low or not ambitious enough (e.g., for CLABSI, C. difficile, and CAUTI).³⁸

Overall, the broad diversity of viewpoints was captured in the June 2009 Professional Stakeholder Engagement Meeting presentation, which summarized feedback received about the prevention targets. The summary noted that “commenters” varied on their aggressiveness with respect to the national targets, with some expressing concern that the targets were overly ambitious, while others were concerned that the targets were not ambitious enough.⁴⁰

5.5.3 Derivation of Metrics for HAI Prevention Targets

While a number of specific comments were submitted on the derivation of specific metrics,³⁰ a broader issue emerged in our interviews with Federal agencies and external stakeholders. A number of external stakeholders representing health care organizations and the quality improvement perspectives, and the Federal agencies that work closely with them, voiced a strong concern that many of the metrics in the Action Plan are epidemiologically derived and thus formulated at the population level. For example, denominators include “per 1,000 device days” or “per 1,000 urinary catheter days.” Concern was expressed that these types of metrics are meaningful for scientific purposes, but are not as intuitive or understandable for the hospital or consumer. For this reason, they may have limited utility in motivating change at the hospital or provider level. Interviewees advised that providers respond more to institutional metrics, scorecards, or adverse event rates, and want actionable metrics that inform their performance in terms that they can understand and use to guide the next steps for improvement.

It was therefore suggested that alternative metrics, more actionable at the hospital or provider level, may be needed to help drive change down to the bedside. Benchmarking research was seen as a potentially important contributor to the development of these metrics. This view was consistent with the HHS summary of feedback from June 2009, in which HHS noted the feedback that measures “need to be useful at the local level.”³⁰

5.5.4 Lack of Attention to Elements of Stakeholder Engagement

Another concern expressed by interview participants, particularly by external stakeholders, was that the Action Plan is focused entirely on HHS and does not clearly define the role of external stakeholder groups or organizations. While most acknowledged that the plan was conceived as an HHS Action Plan, they noted that the problem is so large and complex, it will require substantial input and attention from many stakeholders beyond HHS. Most of these stakeholders believe strongly that they have a role to play in the implementation of the Action Plan and reaching the targets. Several cited the need for operational steps that would help non-HHS stakeholders (providers, associations, consumers, insurers) to understand or clarify how HHS sees their role and what they can do to help reach the targets. This is consistent with feedback about the Action Plan, received by HHS, expressing the desire for more opportunities for stakeholder input.³⁰

While most participants we spoke with indicated that the Federal agencies developing the Action Plan had sought the involvement of, and feedback from, the appropriate stakeholders, interview respondents named a few groups from whom additional feedback might be useful. These included two additional Federal agencies:

- **National Institute of Allergy and Infectious Diseases (NIAID)** – the main NIH institute responsible for basic scientific research on infectious diseases, including HAI-related issues such as antimicrobial resistance and influenza vaccination.¹⁵ Although NIH participates in the Action Plan initiative, NIAID is not represented, and there is currently no active alignment between the Action Plan and the NIAID research agenda.
- **Department of Defense (DoD)** – like VHA, HRSA, and IHS, DoD has direct operational responsibility for the provision of health care services and, like VHA, has active programs related to patient safety.

Other non-Federal stakeholders that interviewees suggested could be better engaged in the Action Plan included:

- Nurses, who are critical to the implementation of many clinical guidelines;
- Hospital housekeeping, which is critical to the maintenance of the environmental aspects of infection control;
- Medical device manufacturers, who may have insight into infection control of device-related infections (catheters, ventilators, etc.); and

¹⁵ <http://www.niaid.nih.gov/Pages/default.aspx>

- A wider range of hospital-related associations (e.g., Society of Hospital Medicine) to provide additional input from the provider perspective.

Most interviewees recognized that the agencies developing the Action Plan had sought, and continue to seek, input from a wide range of stakeholders. The agencies have also demonstrated that they continue to take this task seriously, as indicated in HHS Steering Committee discussions of an upcoming September 2010 stakeholder meeting to revise Action Plan targets and metrics, a main goal of which was described “to engage a wider array of stakeholders. Ideally, we would like the non-federal stakeholders to use this as their plan, not just an HHS plan, so that we create a national movement towards HAI elimination.”³⁷

5.6 Inputs In Relation To the HAI System Framework

In this chapter, we have reported on the inputs—in terms of resources and strategies—to the Action Plan as was developed and implemented in its first year. We have also discussed the perceived strengths and limitations of the Action Plan, as deployed in its first year, from the perspective of internal and external stakeholders. Here we organize the results of the Input evaluation according to the elements of the overall HAI prevention system framework guiding the evaluation (see **Exhibit 2** in Chapter 1). As **Exhibit 14** indicates, many of the perceived strengths and weaknesses of the Action Plan pertain to issues of leadership and strategy, in terms of how to ensure coordination and decision-making among stakeholders.

Exhibit 14: Input Evaluation Findings

Input Evaluation Findings	Element of HAI Prevention System Framework
Perceived Strengths of the Action Plan	
Promise of Interagency Coordination The model and structure of the Action Plan appear to have begun improving communication and decision-making and, to some degree, coordination of operational activities at the Federal level. This issue was one of the main findings of the March 2008 GAO report, which was critical of HHS leadership related to HAI issues. The Action Plan also has gained interest as a potential model of interagency coordination within HHS for other health care quality concerns.	Leadership and Strategy
Selection of Infections for the Action Plan to Address The set of six targeted HAIs within the Action Plan generally is considered to be based on credible criteria that can focus and motivate change by health care organizations and providers. How the focus on two organism-specific priorities can be implemented and how future HAIs will be selected for priority action will depend on additional research and knowledge development. Flexibility and adaptability, as illustrated by the process of addressing HAI prioritization, are also considered a strength of the overall Action Plan strategy.	HAI Prevention Practice Adoption Knowledge Development Leadership and Strategy
Visibility and Accountability for HAI Issues The symbolic value of the Action Plan and its structure is seen as	Leadership and Strategy Infrastructure Development

Input Evaluation Findings	Element of HAI Prevention
signifying an important commitment on the part of HHS leadership to the issue of HAI. The accountability attached to the Action Plan by Congress as well as by HHS leadership also appears to have provided key incentives for cooperation and the strengthening of collaborative relationships and other network infrastructure within and outside HHS.	
Increased Speed of HAI Activities The Action Plan has been perceived by stakeholders as providing the structural basis for increasing the speed of communication and enhancing the Action Plan's capacity to influence eventual adoption of HAI prevention practices by health care organizations and providers.	Infrastructure Development HAI Prevention Practice Adoption
Perceived Limitations of the Action Plan	
Lack of Operational Specification The lack of operational specification is considered a main limitation of the current strategic structure of the Action Plan, hindering the ability to engage stakeholders effectively, at various levels of the health care system, in coordinated efforts to implement HAI prevention practices.	Leadership and Strategy HAI Prevention Practice Adoption
Setting of HAI Prevention Targets This limitation of the Action Plan is partly attributed to the nature of the inputs that the Action Plan initiative has to work with, namely differences in the perspectives of various stakeholders (both internal and external) in the nature and use of prevention targets (i.e., as aspirational/stretch vs. infeasible/disillusioning). Navigating and arbitrating these differences are considered important issues for both the strategic leadership and those developing the evidence base guiding the Action Plan.	Leadership and Strategy Knowledge Development
Derivation of Metrics for HAI Prevention Targets Institutional-level metrics of HAI rates are currently seen as ill-developed. There is a need for metrics that are more useful and motivating for organizational-level improvement efforts.	HAI Data and Monitoring HAI Prevention Practice Adoption
Lack of Attention to Elements of Stakeholder Engagement Despite the extensive efforts of the Steering Committee to elicit feedback from external stakeholders during the development of the initial Action Plan document, a range of stakeholder representatives commented that they have had little input into the Action Plan during its first year of operation, and are generally not aware of the various activities undertaken by the Steering Committee and working groups during that time.	Leadership and Strategy

Research on HAIs (i.e., knowledge development) is particularly important in the perceived strengths of the selection of infections for the Action Plan to address, as well as in helping to improve perceived limitations of the Action Plan related to the setting of HAI prevention targets. The Action Plan has also been viewed as spurring initial infrastructure development and accountability around the Action Plan and strengthening networks and relationships for action. Last, inputs to the Action Plan were perceived as having improved the basis for adoption of HAI prevention practices through the set of priority infections selected on criteria that are credible to health care organizations and providers and by the increased speed of HAI activities. At the same time, stakeholders reported deficiencies in inputs of the Action Plan

related to the operational specification of the Action Plan and the derivation of metrics for HAI prevention targets, both of which were considered to hinder adoption of HAI prevention practices by the institutions and professionals providing health care at the local level.

6. IMPLICATIONS OF OUR RESULTS FOR THE ACTION PLAN INITIATIVES

The first year of the evaluation is intended to go beyond reporting the evaluation results; it is also intended to inform future Action Plan efforts. In this chapter we summarize key implications of the results of the Context and Input evaluations, organized as challenges and opportunities in three specific areas: (1) data/IT system issues; (2) research issues; and (3) implementation issues. Each of these issues was introduced to the Evaluation Team during Year 1 with the expectation that further description and assessment will emerge in subsequent years.

Chapter 7 presents an overview of the first year evaluations and our recommendations based on these implications.

6.1 Data/IT System Challenges and Opportunities

A key finding and recommendation of the GAO report on HHS leadership of HAI issues was the need to establish greater consistency and compatibility of the data collected across HHS on HAIs and to increase the information about HAIs, including reliable national estimates of the major types of HAIs.¹ The expected benefits of achieving these goals include:

- Detecting patterns and trends more rapidly and completely;
- Supporting efforts for public transparency and hospital-level quality improvement to decrease HAI rates; and
- Reducing redundancy and costs for such data systems.

The ability of HHS to attain these objectives, however, is hampered by a number of challenges related to the context of the current health care and HAI surveillance system, many of which can only be addressed through coordination and collaboration with stakeholders in the wider system. The Action Plan has a chapter on information systems and technology, and the initiative established a working group on this topic. The Information Systems and Technology Working Group is charged with aligning data elements and system standards and providing guidance on the integration of HAI data; mobilizing health information systems to reinforce recommended safe practices by providers; and seeking strategic opportunities to make data systems interoperable.⁶ The Research Working Group also addresses a number of data and IT system challenges through its identification of research priorities, such as assessing feasible, valid, and reliable methods for measuring and reporting compliance with HAI prevention practices, and evaluating how electronic data can be used to measure HAI process and outcomes.⁶

Below we examine these data and IT system challenges, as well as related opportunities for addressing these issues, which are grouped into five areas:

- Quality and validity of existing HAI surveillance data;
- Inadequate standardization of current data and IT systems;
- Limited interoperability of these systems;
- Limited scope of data collection; and
- Burden and efficiency of HAI surveillance and reporting systems.

6.1.1 Quality and Validity of Existing HAI Surveillance Data

A range of stakeholders in our interviews echoed the concerns expressed in reports by government agencies¹ and by various stakeholder organizations and representatives³¹ about the quality and validity of the data currently being collected to monitor HAIs. We identified in our interviews and document review a number of contributing factors that underlie these concerns.

- Hospitals vary in their implementation of strategies for finding cases of HAIs⁶ and often interpret the relevant definitions for reporting HAI incidences differently.¹⁵ Additional variation in interpreting these definitions may be introduced because current surveillance systems by necessity rely on the subjective judgment of clinical staff to determine the occurrence of an HAI. As one interview respondent explained, “The systems [use] algorithms to present data on a patient who may have an HAI, but they still need a knowledgeable intermediary to decide if they actually have one.” Poor inter-rater reliability for determining incidences of HAIs has been noted even within a facility.⁶
- Exacerbating the problem, “there is considerable variation from state to state in capacity for surveillance reporting. There is variation within states from facility to facility.” A particular issue in this regard is that hospitals with more effective infection control programs tend to detect a higher proportion of HAIs that occur in their facilities,¹⁵ while hospitals with less robust infection prevention programs are likely not only to have poorer HAI performance but also to under-report infections. In the words of one interview respondent, “One of the problems is that if you don’t look very hard for infections you won’t find them.”
- There is also a general absence of systematic, independent mechanisms for validating HAI data across surveillance data collection systems.³¹ This is especially problematic as data collection systems designed on a voluntary reporting model, such as NHSN, are increasingly applied to mandatory public reporting initiatives, particularly at the State level. Without an independent verification process, mandatory reporting systems run the risk of encouraging hospitals to be less rigorous in seeking to detect HAIs, since the fewer they find, the better they look compared to competitors.¹⁵ While the CDC has collaborated with States that adopt NHSN to develop methods to ensure that submitted data are accurate, States and hospitals within them face substantial technical and fiscal

constraints in implementing such mechanisms, which can require considerable staff resources.¹⁵

Interview respondents also pointed out that, even with valid data, there remains the difficulty of interpreting rising rates—whether as a true rise in infection events or as an artifact of better reporting. This is especially a problem in comparing relative rates across States or sets of facilities at various stages of maturity in surveillance and reporting systems.

- While creating challenges, mandatory State reporting and other public reporting systems also present opportunities for improving the quality and validity of HAI data. In particular, these reporting systems require or place pressure on hospitals to report data on HAI prevention practices and outcomes.³¹ For example, one interview respondent noted, “There is a huge initiative (both at the state and national levels) about reporting these infections.... I think an expanded [national HAI surveillance system] could yield great insights into HAIs.” Such developments help to increase the representativeness of the data, which to date has been a critical limitation on the generalizability of information from these systems.¹¹

Moreover, the rising use of HAI surveillance and data collection systems for public reporting is likely to intensify pressures for developing validation mechanisms to verify the accuracy of data that may have competitive consequences. For example, as hospitals and health systems are called upon to invest in systems to monitor and publicly report HAIs, while simultaneously being reimbursed in relation to HAI-associated rates (as in the case of value-based purchasing and pay-for-performance reimbursement systems), the scientific validity of the reporting of facility-based rates of HAIs and adoption of processes supporting HAI prevention is likely to come under increasing scrutiny.

6.1.2 Inadequate Standardization of Current HAI Data and IT Systems

A major factor limiting the ability to aggregate and fully leverage the various HAI data currently collected is the lack of sufficient standardization among existing HAI data and IT systems. In addition to variation in how clinical definitions or case finding methods are interpreted, as noted above, the definitions and methods themselves vary between systems, in many cases in relatively arbitrary ways, reflecting derivations that span time and place. The stakeholders we interviewed and the documents we reviewed noted this challenge in terms of metric definitions, data collection methods, and IT system specifications.

For example, the GAO highlighted that the varying content and methods used to collect and report data on HAIs across HHS’ four main databases have precluded the department from combining data. Even databases that collect information on the same HAIs calculate and report rates in ways that are different and difficult to reconcile.⁴¹ The ability to identify and connect information on individual patient cases across data systems is also important in order to link HAIs manifesting after hospital discharge back to inpatient procedures. This is also hampered by formats that are not identical across systems.⁴²

Considerable progress has occurred in identifying and comparing data and IT system definitions, particularly those related to HAI metrics, but much more work is still required to reconcile the definitions used in practice by these systems.¹¹ Broader efforts to standardize health care data systems and exchange, such as Common Formats and Clinical Document Architecture (CDA) for electronic health records (EHRs), also represent opportunities for harmonizing data element definitions both within HHS and between HHS and external data systems.⁴² One of the interviewees stated that with CDA, “clinicians can do what they want, but in the end all their machines can be shared and analyzed together.”

Many stakeholders we interviewed believed that the NHSN system has improved standardization and offers the best current platform for a national HAI data system. As one interviewee stated, “Having NHSN working with hospitals has had some effect on standardization. I think it’s going to become the de facto data center.” The GAO similarly noted that virtually all States with public reporting requirements for HAIs use NHSN as the required hospital reporting system, and most of the programs that do not use it still draw on CDC’s clinical and reporting definitions.¹⁵ However, the stakeholders we interviewed also raised concerns about the burden on hospitals for installing and using the NHSN system (described further below).

6.1.3 Limited Interoperability of Current HAI Data and IT Systems

As one of our Federal interview respondents stated, “System interoperability is an issue including interoperability with hospitals, vendors and [government agencies]. We need a system that does not require data to be re-entered.” Another Federal respondent concurred, “The last thing we want to do is have more than one Federal agency asking for the same thing.”³¹

The inadequate standardization described above is a central contributing factor to the lack of interoperability among HHS and other HAI data and IT systems. However, as one stakeholder we interviewed emphasized, “We want ... a level of integration that’s more than just compatible ... [we want] systems that readily communicate” and interface with each other. This level of interoperability is necessary to leverage advances in state-of-the-art information technology to detect HAIs more rapidly and completely (e.g., through computer-based detection algorithms and automated intelligence systems) and to provide timely support to both hospital quality improvement efforts and public health monitoring (e.g., rapid detection and “early warning” of HAI patterns and trends).⁶

In addition to adequate standardization, this level of interoperability requires establishing appropriate technical interfaces between systems, automation of data finding and transfer tasks, and cooperative arrangements among data owners.⁴² Rather than merely relying on the retrospective integration of databases, this level of interoperability also requires proactive integration at the front end, where data originates,⁶ including not only current HAI surveillance systems, but also other repositories of HAI information, such as electronic health records (EHRs), health information exchanges, and hospital-level patient safety event reporting

systems. Underscoring the difficulty of creating interoperability across this diversity of systems, an AHRQ-sponsored survey found that fewer than half of hospitals with event reporting systems collected information on HAI events, and roughly 40 percent of those that did collect this information used minimally automated, paper-based reporting systems.⁴²

Fortunately, a variety of opportunities exist to collaborate with private and other public entities to promote, manage, and implement widely adopted health care data and technology standards.⁴¹ These opportunities include leveraging the standards and process development occurring through the “meaningful use” movement in the health IT sector, working with major vendors of EHR systems, collaborating with health information exchanges that allow for aggregation of EHR data and with the Nationwide Health Information Network (NHIN), which seeks to establish a secure interoperable information infrastructure linking regional health information exchanges, participating in large-scale initiatives that can be used to shape the development of HAI information architecture, such as the Federal Health Information Sharing Environment (FHISE), and applying the National Information Exchange Model (NIEM), a use-driven approach gaining recognition among Federal agencies for achieving interoperability of information systems.⁴²

6.1.4 Limited Scope of Data Collection

Stakeholders we interviewed identified several shortcomings in terms of the scope of data presently collected in HAI surveillance systems. The first limitation relates to the range of settings currently represented in HAI data systems. As described by an interview respondent, “The focus of much of the HAI monitoring is on hospitals, and it’s on certain types of infections, but we know that HAIs occur outside of the hospital, for example, with ambulatory surgical center populations. And we know that some HAIs get at soft tissue infections where we don’t have as much information as we would like. As a result of those gaps, when we ask, ‘What’s the total number, what’s the total mortality?’ we’re less equipped to answer those questions than those that focus on a more discrete set of infections in discrete locations.” Consumer organizations and other stakeholders have similarly commented on the lack of attention to HAIs in health care settings other than hospitals, such as ambulatory surgical centers and long-term care facilities.³⁸

Another interview respondent noted a relative dearth in data collection of process measures, which are useful to “see if we are getting people engaged in the reduction of HAIs” and would provide leading indicators of possible future reductions in HAI rates. Finally, the scope of the sample of hospitals currently participating in HAI surveillance systems may not only be limited and non-representative, but also possibly biased in misleading ways. “A weakness is the completeness across the hospital [population]; not everyone is submitting data about their HAIs. Not everyone is participating in the data submission; some states require participating while others don’t. Most participants are hospitals that were already motivated to reduce HAIs.”

6.1.5 Burden and Efficiency of HAI Surveillance Systems

As noted in the Action Plan itself, current HAI surveillance strategies are labor intensive,⁶ and, as others have argued, the strategies place substantial burden on hospitals and providers. If these burdens were relieved, that would improve reporting and free up resources for prevention efforts.⁴¹ Our interview respondents made similar observations. For example, “The hospital community wants safety for their patients but have a tremendous burden in reporting, so we are working to see how we can get the surveillance data we need without adding much burden.” As discussed above, several stakeholders we interviewed, including hospital and provider representatives, specifically focused on the difficulties with the NHSN system, variously describing it as “cumbersome to work with,” “cumbersome to install and use,” “problematic to implement,” and generally “burdensome” for hospitals.

Opportunities suggested by respondents to address this burden include enabling interfaces between EHRs and the NHSN system and, as mentioned previously, working with third-party vendors of EHR systems.⁴¹ A few interviewees, even while recognizing the present usefulness of NHSN, questioned whether it is the best platform for the future as hospital-based health IT and reporting systems develop. Although this opinion was shared by a small minority of respondents, one described it as an “issue that needs to be addressed ... the conundrum between preparing measures to be used with electronic health records and needing to use NHSN now to prepare the measures.... Investing in [NHSN] is like putting money into a system that will soon be obsolete. But if we don’t do it, there won’t be any data. It’s very important that we find the right balance.”

6.2 Research Challenges and Opportunities

When asked about research needs related to HAIs, stakeholders in our interviews identified a wide range of areas and, in particular, the need to prioritize research efforts given the limited resources available. As a senior Federal administrator remarked, “The plan is very comprehensive in addressing the important research areas. The problem is how to prioritize the issues. We can’t fund everything.” Similar concerns have led members of the health care epidemiology community to call for a national research agenda, national research consortium, and a general increase in HAI-related research funding.⁴³

The Research chapter of the Action Plan organizes the gaps in HAI knowledge and practice into three broad categories: (1) basic and/or laboratory science, (2) epidemiology, and (3) prevention practices.⁶

Our interview respondents elaborated on these categories and emphasized several additional research areas they considered important. The following list includes this full range of research priorities (ordered on a rough continuum from basic to applied research).

6.2.1 Basic Biomedical and Epidemiologic Research

Topics in this research area include the pathogenesis (e.g., biofilms, toxins, virulence factors, mucosal immunity), transmission, and colonization dynamics of specific microbes across different settings, which are still not well known for many organisms that cause HAIs.¹³ This is especially the case with multidrug-resistant organisms, which were described in the interviews as “a huge looming problem” that “needs a lot of attention and focus.” Other critical gaps mentioned in basic biological and epidemiological science include the value and effectiveness of screening strategies, and evidence to inform the movement for antimicrobial stewardship.

6.2.2 Effectiveness of Known Prevention Practices

Similar to published assessments of current practices,¹³ our interview respondents from an epidemiological background were highly skeptical of the evidence supporting current preventive practices, viewing many of them as based more on experience and supposed common sense rather than on a scientific evaluation of efficacy and effectiveness. Thus, building the evidence base for existing practices was seen as critical to avoid unintended consequences of ineffective interventions, and unnecessary diversions of limited infection control resources. This concern was heightened for newly spreading practices that appear to be “emerging ahead of the science” (e.g., MRSA decolonization).

6.2.3 Identification of New Prevention Strategies

Interview respondents also called for “increasing the research on identifying new methods for reducing HAIs.” Similarly, ensuring that new preventive practices are scientifically supported was considered critical, as expressed by a respondent from a purchaser and improvement background: “We need to determine which strategies are supported by evidence. One wants to use evidence-based interventions.” Another respondent called for “evidence around preventing infections generally” in addition to specific HAIs, because such broad-based approaches may provide more comprehensive and cost-effective strategies for preventing infections, including emergent pathogens that are not well studied.

6.2.4 Benchmarking of Targets

Several respondents discussed the importance of using evidence to set appropriate and achievable targets for practice adoption and HAI outcomes. “Intervention targets are also very complicated and not really based on evidence. This gets back to the prioritization.” But “people are reluctant to get involved with benchmarking. We need to determine where these rates should be. This should be the first priority and it hasn’t happened.”

6.2.5 Implementation and Dissemination Strategies

Respondents and documents highlighted implementation and dissemination strategies as the main focus of the Action Plan. Key topics in this research area include how to encourage the

adoption of HAI prevention practices by hospitals and providers, understanding why there is poor adherence to these practices, and how exploring electronic data and IT systems can be used to encourage adherence to practices and measure HAI prevention processes and outcomes.³¹

6.2.6 Effectiveness of General System Change Strategies

The interviews also identified a need to build credible evidence for strategies increasingly being implemented at the level of the health care system as a whole, such as the effects (intended and unintended) of public reporting systems, campaigns to activate patients and families in HAI prevention, and pay-for-performance and other incentive programs.

6.2.7 Synthesis of Current Research Findings

It was also noted that the scientific evidence on HAIs and HAI prevention and implementation practices is voluminous and continually growing. As a result, assessment of current scientific findings is necessary to usefully aggregate knowledge for specific HAI issues as well as to identify gaps in knowledge for future research. “The big challenge ... is to get a handle on the research ... and do a synthesis of that to make sure it gets fed into future planning and future funding.”

Although the Action Plan is explicitly oriented toward prevention of HAIs, consumer stakeholders we interviewed contended that a national effort also must address the care of patients once an infection is contracted, in particular, best practices for patient and family disclosure, discharge from acute care facilities, and community follow-up.³⁸ If the scope of the Action Plan were to include HAI care as well as prevention, then these issues would represent additional priorities for HAI research.

As discussed above, most interview respondents identified difficulties in prioritizing research efforts across such a diverse set of critical topics. Yet some respondents with strong opinions were divided between those who believed enough evidence on effective practices exists to focus research on implementation, and others who believed that much more basic epidemiological and clinical science is still required. For example, one commented, “if we just consistently implemented the infection control practices we have on the books, we could reduce infections by 70 percent.” In contrast, another respondent stated that although “the major effort has been on implementing practices that we believe are effective in preventing HAIs, I think one could argue that it would be just as good to focus some more effort on studies designed to elucidate basic pathogenesis and epidemiology of HAIs.... We need to understand what the knowledge gaps are in terms of pathogenesis, and we don’t know enough about the microbes themselves.”

Advocates of this latter stance also emphasize that the risks of implementing practices based on inadequate scientific understanding are exacerbated when mandated by regulatory and payer requirements, as is currently the trend.⁴³ They claim, moreover, that even though successful

implementation of strategies already known or suspected to be beneficial may provide immediate short-term benefit, investments in basic science, translational medicine, and epidemiology are needed to move progress to higher levels in the longer term. These differing perspectives and claims for research represent potential points of contention given limited resources. Additionally, they reflect underlying tensions between the epidemiological sciences community and the quality and safety improvement community, as was noted in the Context evaluation in Chapter 3.

Differences in these perspectives notwithstanding, other interview respondents stressed the importance of the evidence base on HAIs and prevention practices—both basic and implementation research—for prioritizing Action Plan efforts as well as for prodding health care organizations and providers to make changes: “We need strong evidence to get a buy-in. Other evidence is not ... compelling enough.... We need better evidence to convince the hospitals to comply.”

6.3 Implementation Challenges and Opportunities

A key criticism in the GAO report was that although HHS agencies had delineated a large number of evidence-based recommended prevention practices, a lack of prioritization hindered efforts to promote their implementation by health care institutions and providers.¹ The Action Plan has a chapter on prevention and implementation, and the Prevention and Implementation Working Group is charged with prioritizing existing recommended infection control clinical practices.

Yet prioritization of interventions, albeit important, is only one challenge to ensuring the adoption and implementation of effective prevention practices within the health care system. As the Prevention and Implementation Working Group itself has recognized, there is a need to better understand why some recommendations are not implemented and why some providers do not comply with identified evidence-based practices. Consequently, the working group also includes in its charter the goals of identifying opportunities to share best practices that result in successful HAI reductions and prevention and of enumerating strategies to translate prioritized guidelines into bedside care. The Research Working Group similarly has recognized the implementation challenge, identifying the need for additional research on the human and organizational factors affecting adoption and implementation of practices, the effectiveness of new technologies to aid implementation, and standardized methods for measuring and reporting compliance.⁶

The stakeholders we interviewed and the documents we reviewed discussed a wide range of implementation challenges and opportunities. In this section, we organize these comments and insights into four areas: depth and breadth of implementation, leveraging infrastructure, resource sufficiency, and building and sustaining momentum.

6.3.1 Depth and Breadth of Implementation

A common theme in the interviews was that sustaining reductions in HAI rates will require driving change across levels of the health care system down to the bedside. As one interview respondent commented, “We can have this great grandiose plan, but if it isn’t implemented where the consumer and the system collide, it won’t have any impact.” In the words of another respondent, “The big challenge ... is bringing this to scale ... people don’t know how to do it ... how do we get there, how are you going to change the practice on the ground at X hospital?” In addition to the challenge of depth, others noted the challenge of breadth of implementation across various settings and sectors of care; one respondent stated, “There is a tendency to focus on hospital medicine; there are other types of facilities that are just as important.”

Interview respondents pointed to a number of strategies for driving change through multiple levels and across settings of the health care system. In addition to the issuance of guidelines and required standards of practice, two methods prominently discussed were financial and transparency incentives.

- **Financial incentives** – Within the Federal sector, CMS’ unique control over health care reimbursements through Medicare and, in particular, its developing policy to not pay hospitals for treatment of HAIs, was considered “an extremely large hammer” and a “big stick to force changes.”³¹ Such changes to reimbursement policies in Medicare and Medicaid were seen as a means to spur changes in the private health insurance sector. The GAO also emphasized the role of CMS and its power of the purse.¹
- **Transparency incentives** – Transparency involves providing information on the performance of individual health care organizations and clinicians to stakeholders in the system including consumers, payers, regulators, and other providers. The GAO has emphasized the role that HHS agencies can play in releasing data on HAIs to expand information about the nature and extent of the problem. Others have emphasized a strategy of publicly reporting data on the performance of individual hospitals and other providers, such as through CMS’ Hospital Compare Web site, as a means to encourage providers to benchmark themselves against competitors and to influence the choices of consumers and health plans.³¹ Consumer groups, in particular, have advocated for mandatory public reporting systems, both at the State and national levels.³⁸

Several interview respondents, while agreeing that financial and transparency incentives are important tools, judged them insufficient for producing the deeper changes to organizational cultures and work processes necessary to implement and sustain HAI prevention practices. “The usual approach to QI is focused on measurement and that is not enough.... Measurement and transparency are the incentives to get there and get you started. By themselves they don’t make changes.” Another interview respondent similarly bemoaned common simplistic approaches to implementation: “The perception is that the only thing that is needed is to increase adherence to checklists.” A third respondent emphasized the human and social factors at play, “You can sustain [improvement] if you can change the culture.”

Challenges to this relatively more nuanced picture of implementation included the following:

- **Leadership** – While leadership can take many forms at many levels of the health care system, the interviewees emphasized leadership at the Federal level within the Action Plan. Some respondents emphasized having “strong leadership” to corral the various agencies and committees involved in the implementation of the Action Plan. Consumers groups, in particular, have advocated for someone “who can command action,” especially in the face of a health care industry they consider generally slow and resistant to make improvements related to HAIs.³⁸ Others focused on a more persuasive, consensus-building form of leadership, with a desire that such a role become “institutionalized” within HHS.
- **Clarity of plans and execution** – A number of interview respondents stressed a need for not only goals, but also the means to drive their implementation through the system, to be clearly planned and communicated. One respondent underscored the need to “clarify the steps required to move from point A to B,” and another, the importance to “think ... strategically ... to address our progress with each goal and what else needs to be done to achieve these goals.” Comments on the Action Plan by epidemiology and infectious disease professionals argued for “well-defined action items,”¹⁶ and consumer groups called for “bold recommendations and specific actions,” with an added emphasis to back them up with “government oversight and mandates.”³⁸
- **Infrastructure for implementation** – A key enabler to driving changes identified by a range of respondents is an infrastructure at various levels that supports the communication and spread of new ideas and the coordination of resources and action. Some interview respondents discussed infrastructure at the Federal level as well as in the private sector, for example, associations that represent and speak to important stakeholder groups, such as the American Medical Association and the American Public Health Association. GAO reports also have highlighted infrastructure both in the public sector and the private sector, and the links between the two, such as the Medicare Conditions of Participation (CoPs) for infection control being satisfied through Joint Commission accreditation of hospitals.¹ Some respondents noted that a substantial amount of ARRA stimulus funding went to the States with the explicit purpose “to build infrastructure at the local level—to write State plans, hire [HAI] coordinators, and develop IT infrastructure.” Yet concerns over the adequacy of the infrastructure were still voiced: “The infection prevention groups [in hospitals] have existed for 20 years; some small hospitals do not have them. There is some existing infrastructure, but it may not be enough.”

6.3.2 Leveraging Infrastructure

In general, most stakeholders we interviewed believed that infrastructure exists at State, regional, and local levels to implement changes, but that it varies considerably. It was also

¹⁶ SHEA /IDSA Comments on Action Plan, 020609

noted that HHS agencies do not have operational authority to align non-Federal stakeholders: “We can bring our stakeholders on board but don’t have the power to align their resources.” Although certain Federal agencies such as the VHA, Department of Defense, and Indian Health Service are responsible for directly providing health services, other Federal agencies can “put it on the front burner and nurture it with money, but it’s hard to say you ‘implement’ when you don’t take care of anyone.”

Consequently, partnering and outreach with private and State-level stakeholders was considered by many we interviewed to be critical to the success of the Action Plan.³¹ “There is a tendency to make the problem and the solution a Federal one. It’s bigger than that. While the Action Plan recognizes that and gives due credit to the whole notion of broadening the effort, how do we do that is part of the challenge. That’s an area, opportunity to strengthen....” Others agreed that “building those partnerships with health quality organizations, consumer groups, etc., continues to be an effort.” An especially critical level of the health care system that some targeted was top executive and clinical leadership. These are the people who draw attention, provide resources, and often authorize new initiatives within their organizations. “Reduction of rates can’t happen without clinical and administrative leaders. If they aren’t involved nothing substantial will happen.” “It’s not just educating the doctors....If management isn’t involved, it’s history. It’s got to be top-down and bottom-up.”

One difficulty in working with State and local entities that are responsible for prevention of HAIs is their diversity, in terms of their numbers and types, as well as their variable infrastructure and capacities. “One of the challenges is that each state had a different level of focus on this issue prior to [the Action Plan]. Some already had mature and advanced efforts in reducing HAIs, and others had modest and immature efforts. Developing efforts that work on this continuum was and continues to be a challenge.”

At the same time, the capacity of HHS agencies to leverage and coordinate the infrastructure at these other levels is fragmented and somewhat underdeveloped. Individual Federal agencies have experience and have developed specific programs to implement changes, with organizations and providers delivering direct services. For example, AHRQ has worked closely with the American Hospital Association, which is “made up of all the state hospital associations. CDC tends to go to state health departments, and you have QIOs from CMS. That way at the local level you have three different points of contact.” Likewise, another respondent described how “each operational agency has state and regional outreach. CDC has long-standing relationships with State health departments and make sure they are involved in the effort. CMS has State accrediting bodies and making sure they have detailed infection control. We are trying to make linkages at the State level that we see nationally.”

The central challenge is how to connect and coordinate the varied infrastructure of HHS agencies for implementing change within the health care system into larger set of conduits that work together effectively, and how to do so efficiently.³¹ In the words of one interview respondent, there is a need “to build one infrastructure across infections (not individually for

each one), and also we should use the infrastructure already built by other quality efforts. Right now, there is no definable infrastructure.”

6.3.3 Resource Sufficiency and Predictability Over Time

The adequacy of resources to maintain implementation over the longer term was also a concern voiced by a number of respondents, despite recognition of the relatively generous funding for HAIs by Congress and the States and the role of these monies in developing infrastructure for future change.

One worry is that although current funding has supported much research and planning, there have been, in the words of one respondent, “insufficient resources to implement,” a concern echoed by various HAI stakeholders related to HAI prevention staffing, training, planning, and reporting.³¹ Another interview respondent pointed out that even if relatively few resources have been allocated to implementation to date, “in some ways, some of the money has been used to develop the infrastructure that [health care delivery organizations] will need to carry on, mainly in the area of information technology. Hopefully some of the infrastructure that’s been built will help them carry on.” Even so, a concern remains that despite the support for infrastructure, there is still uncertainty as to how HAI funding will be funneled down to local implementation, and how front-line delivery organizations will be able to justify and fund local HAI prevention efforts. “In order to do all of this, we have to be able to pay for it. Money is an area that needs to [be focused] on. What are the evidence-based interventions that are available, and how are we going to pay for implementing them?”

6.3.4 Building and Sustaining Momentum

Finally, our interview respondents identified the building and spread of enthusiasm for tackling the problem of HAIs as both a challenge and an opportunity. As discussed in Chapter 3, HAIs have attained high visibility and are now generally viewed as preventable. Given this context, the opportunity to see one’s efforts contribute to relatively quick and meaningful change can be highly motivating. In the words of one interview respondent, “I work on other public health issues, so it’s really exciting to work on this. You can implement things in a unit, and you can see the BSI rates drop, and they can sustain it.... We can actually do this in my lifetime, in my career. I don’t think we can eradicate HAIs, since we can’t get rid of the underlying pathogens, but we can make some huge progress really quickly.” Indeed, early gains are often used as a strategy to garner buy-in and momentum for large-scale change efforts. As the initiative grows in size and complexity, however, it can be a challenge to “not just expand, but to expand and sustain the excitement as we move into new areas.” The objective of such a process, in the words of another respondent, is for the Action Plan to be “seen as a starting place, and not an ending place. I hope that successes within the first few years will breed further attention and funding. I think it has to be a long-term proposition.”

7. SUMMARY OF FIRST-YEAR EVALUATIONS FINDINGS AND RECOMMENDATIONS

Overall, the goal of the Action Plan is to improve adoption of evidence-based processes known to reduce HAIs and to reduce HAI rates. The Action Plan was launched in response to a series of events that led to a GAO report that documented a fragmented approach to the emerging HAI epidemic. In the context of these events, the Action Plan considered a variety of inputs (structures and processes) that are expected with implementation to support the goals of the Action Plan.

In this report, the IMPAQ/RAND team has examined the Context and Inputs of the HHS Action Plan with a focus on the evaluation of these phases of the initiative. As intended, the application of the CIPP Model allows both descriptive information and judgmental assessments to inform the evaluation. The criteria used for judgments include concordance with policy makers and stakeholders, comparisons with other programs and with the scientific literature. It is expected that with subsequent (Year 2 and 3) reports that the proportion of evaluation relying upon criterion judgments will surpass those relying upon descriptions. However, across all reports, in aggregate, the Context and Input evaluations will serve as a historical record documenting the context in which the Action Plan was introduced, an assessment of its initial programmatic and resource inputs, and an analysis of key issues affecting its continuing implementation. In this chapter, we summarize these findings and present recommendations intended to help guide the strategic direction of the Action Plan.

7.1 Context Evaluation

In Chapter 4, we described the contexts and the multitude of decisions that the Action Plan considered in defining its goals. As shown in **Exhibit 10** (Findings, Recommendations and Implications of the GAO Report, March 2008), **Exhibit 11** (Legislative and Regulatory Policy Related to Action Plan Activities), and Exhibit 12 (Policy Mandates and Expectations for the Action Plan), the Action Plan was implemented in the context of a rich set of recommendations, legislative and regulatory environments, policy mandates, and expectations. The Context evaluation supplies information about the strengths and weaknesses of the system that can facilitate planning goals and objectives. Accordingly, this evaluation report included an assessment of the extent to which the Action Plan, in identifying its goals, identified the strengths and weaknesses of the systems that could be leveraged to support successful achievement of its goals and objectives. The Context evaluation revealed that HHS, through the Action Plan, has made an impressive assessment of the needs, problems, assets, and opportunities for a program that will help decision-makers define and judge goals, priorities, and outcomes. It showed that HHS considered quite thoroughly and thoughtfully the state of affairs prior to the start of the HAI initiative. The antecedent state's impact is apparent in the way the Action Plan focused on the key themes of legislative and regulatory policies. The evaluation revealed that the goals were tied to a timeline of events and legislation that led to the development of the Action Plan and its goals. Records of the prevalence of HAIs prior to

the Action Plan, HAI-related programs that already existed, legislative action related to HAI, and awareness of research efforts that focused on HAI all contributed to the development of the Action Plan goals.

The Context evaluation described the objectives of the Action Plan, why they were selected, and what assumptions were made, and also specified limitations in extant structures required to support the stated Action Plan goals. Recognition of these limitations is one type of context that motivated the development of the Action Plan. In this way, the Context evaluation provides a fundamental kind of accountability that helps to answer questions about program and project objectives.

This Context evaluation showed that the goals of the Action Plan were developed with an understanding of the needs and assets that existed at the time it was formulated. In this way, the Action Plan was in a position, from the beginning, to inform future structures and decisions regarding goals and objectives. With this statement of explicit goals and objectives, HHS from the beginning has been in a strong position to determine whether new objectives should be added or present ones be changed. Based upon this information, the Context evaluation concluded that the objectives chosen and the reasons they were chosen are clear.

The goals, including the policy mandates and expectations of the Action Plan are listed below:

- Reduction of duplicative efforts and increased cohesion of HAI activities among agencies within HHS. (Processes and outcomes)
- Alignment and coordination of HAI prevention efforts and resources across Federal, State, and local levels. (Structure and processes)
- Standardization and interoperability of HHS data systems for surveillance and reporting of HAI incidence. (Structure)
- Prioritization of HAI prevention practices. (Process)
- Expansion of scope from acute care hospitals to other health care settings, including ambulatory and long- term care facilities. (Structure)
- Substantial reductions in rates of targeted HAIs over time. (Outcomes)

These goals are directly responsive to the concerns of the GAO report, to the emerging consumer and patient safety movements, and to the expanding evidence base associated with the scientific pursuit of HAIs across the range of basic to implementation sciences. Action Plan goals address structure, processes, and outcomes.

In the explicit statement of goals and objectives that were directly responsive to the identified contexts, the Action Plan should be given very high marks. In the very short time window from the release of the GAO report to the introduction of the Action Plan only a few months later, HHS recognized key contexts and established goals directly responsive to these contexts. A broad set of activities was initiated in a timely manner in response to the context that

motivated the development of the Action Plan. Again, for this reason, the Context evaluation assigns very high marks to the Action Plan.

7.2 Input Evaluation

In Chapter 5 we presented the inputs or strategies considered by the Action Plan pertinent to how the Action Plan should be organized to achieve its goals. The Input evaluation considers the alternative options that might have been selected or structured to support the Action Plan's objectives, and the strengths and weaknesses associated with these options. To achieve this, the Input evaluation identified and assessed details that define the alternative program strategies that should have been considered for achieving the plan's objectives and for supporting strategies to structure decisions and programs. One component of the Input evaluation is the assessment of the degree to which needed resources, personnel, and procedures have been conceptualized, planned, and made available as various decisions and alternatives for supporting goals and objectives were specified.

More specifically, the Input evaluation assessed the intents of the Action Plan and the approaches for realizing these intents by considering the extent to which the strengths and weaknesses of various alternative objectives for implementing Action Plan goals were explicitly identified and acted upon. This includes the development and use of evidence-based processes to improve the incidence of infections, and efforts to support the coordination, data alignments, and implementation of data to characterize and reduce rates of infection. Initial efforts conducted under the Action Plan recognized the complexity required to mitigate infections in the context of mixed opinions about targets and metrics, insufficient operational details, insufficient attention to stakeholder engagement, the enormous scope of the effort required to mitigate infections, and the lack of well-coordinated pieces associated with infection control.

The identification of potential inputs or programs, projects, and activities—in response to a myriad of challenges—has provided tremendous opportunities for supporting the goals of the Action Plan. In this report, we reviewed multiple inputs or activities that have been considered or pursued by HHS under the Action Plan. Our evaluation notes that within a brief time window, a large number of opportunities for possible implementation have been identified; this is a marker for substantial productivity. However, evidence for systematic evaluation of the advantages and disadvantages or costs and benefits of these potential inputs has not been explicit. Strategies for identifying the best set of inputs to support the Action Plan—either in aggregate or within working groups, or pertinent to specific goals—could be made more explicit as a means of allowing review by others and providing transparency to stakeholders with respect to decision-making. While multiple strategies have been specified, stakeholder engagement and long-term effectiveness could be improved by more transparent recording of how inputs were evaluated and prioritized for potential implementation. This is an area that should receive more effort in the future.

Overall, we have identified three areas in which striking balance between potentially competing activities or approaches may improve the adoption of evidence-based infection control methods and, as a result, improve HAI rates. First: balancing efficiency of stakeholder participation versus representativeness. The value of buy-in from a broad and diverse set of stakeholders has been and remains critical. The complex requirements for both efficiency and representativeness have been apparent throughout efforts to coordinate activities, set goals, and communicate with stakeholders. Second, balancing the demands of population sciences versus institutional management has been clearly applicable to infrastructure, data, and science. Limitations of available science and the need for new and expanded scientific methods and analyses, including both implementation and translational sciences, remain apparent. Additionally, the need for expanded research to support both effectiveness and buy-in has been noted. Third, balancing short- vs. long-term goals and accomplishments will continue to be important as the initiative seeks to compete for priority status and available resources while also pursuing its ultimate goals.

Finally, the Context and Input evaluations have provided insights into the forthcoming Process and Product evaluations, which will involve understanding how the efforts under the Action Plan have responded to opportunities to coordinate by building upon thriving movements—safety and translational and implementation sciences—and to align data systems with current quality improvement and “meaningful use” efforts. In this regard, evolving principles of community participation may become pertinent. All of these considerations have been factored into the Input assessment by the IMPAQ/RAND evaluation team.

7.3 First-Year Evaluation Marks and Recommendations

In the Input evaluation, we attempted to understand the degree to which available options were categorized in terms of strengths and weaknesses. As noted in Chapter 1, the Input evaluation includes consideration of which strategies and designs were identified and selected, as well as the reasons for their choice, as a means of being accountable for responsible spending. **Exhibit 15** lists key input elements according to the IMPAQ/RAND evaluation, using categories of *strengths* and *opportunities*. Understanding input elements where the Action Plan received high marks is important so that these areas can be emulated in the future. Understanding the ways in which input elements could be improved provides the opportunity to focus Action Plan resources as we approach the implementation of high priority processes.

Exhibit 15: First-Year Evaluation Marks and Recommendations for Key Input Elements of the HHS Action Plan to Prevent Healthcare-Associated Infections

Input Element	Strength	Opportunity
Identifying the resources available for performance of the Action Plan	<p>The Action Plan has attracted substantial public policy and funding support for Federal planning and implementation. Leaders of key HHS agencies and divisions have contribute divisibility, accountability, and resources for Action Plan activities and coordination.</p> <p>Policymakers have also provided substantial financial and regulatory support to stimulate HAI prevention capacity and activity at the State level, particularly through the ARRA legislation.</p>	<p>Despite the relative generosity of public funding for HAI-related activities, the predictability of accessing needed funds has occasionally been limited, resulting in funds often becoming available late enough that planning how to best use the funds has been difficult.</p> <p>Resources to support regional and State activities, particularly beyond the 2 years of ARRA funding, are limited, and the availability of sustained financial support is uncertain.</p> <p>Resources to support local health care delivery systems and providers to develop and implement HAI prevention programs are scarce. Differences of opinion exist regarding the degree to which the health care industry (e.g., hospitals and clinics), as compared with public sources, should be responsible for the resources needed to reduce HAI rates.</p>
<p>Evaluation Summary: While the Action Plan has attracted substantial public policy and funding support, the lack of predictability and sustainability of funds leads to inefficiencies with available resources and lack of deliberate consideration of the advantages and disadvantages of various alternative strategies for implementation HAI processes.</p> <p>Recommendation: Aim for a baseline sustainable budget to support core activities that will be in place for at least several years, with various projects being considered and implemented as budgets expand and contract. The predictability of this approach can support more effective input strategies.</p>		

Input Element	Strength	Opportunity
Engaging the relevant Federal agencies to lead and implement the Action Plan	HHS has been highly effective in promptly identifying and incorporating most of the key Federal organizations with relevant expertise and assets to lead and implement the initiative.	Although NIH has actively participated in the Action Plan since its inception, the main NIH institute responsible for basic scientific research on infectious diseases, including HAIs—NIAID—is not represented, and there is currently no active alignment between the Action Plan and NIAID’s research agenda. The Department of Defense also has not been fully engaged in the Action Plan, despite being one of the few Federal agencies that directly provides health care services and has active programs in patient safety.
<p>Evaluation Summary: Although HHS promptly engaged almost all the relevant Federal agencies relevant to leading and implementing the initiative, there are two exceptions—the National Institute of Allergy and Infectious Diseases (NIAID) and the military health services within the Department of Defense.</p> <p>Recommendation: Make explicit efforts to engage NIAID and the Department of Defense and integrate their expertise and assets into the Action Plan.</p>		

Input Element	Strength	Opportunity
Encouraging interactions among Action Plan agencies and the coordination of their roles and responsibilities	HHS has repeatedly highlighted the importance of interactions among key organizations and coordination of roles and responsibilities. Inputs from the Steering Committee and working groups support these interactions.	Explicit strengths and weaknesses associated with competing strategies have not been consistently apparent.
<p>Evaluation Summary: The goals of the Action Plan emphasize well-coordinated interactions. While structures have been established to enhance communication and coordination, the complex web of interactions among organizations, policies, and stakeholders that could effectively function in synchrony to support Action Plan goals is just beginning to be identified. While substantial effort toward coordination has been made, as Year 2 of the Action Plan begins, with its focus on implementation of processes, additional insights into networks and relationships among key agencies and stakeholders may be useful.</p> <p>Recommendation: Develop an inventory of organizational goals, projects, and programs associated with the Action Plan as a supplement to the HAI Data Inventory developed during the first-year evaluation.</p>		

Input Element	Strength	Opportunity
Engaging and leveraging various stakeholders in the Action Plan	HHS has consistently engaged external stakeholders and has recognized the need to leverage their strengths as partners in stimulating change across sectors of the U.S. health care system over which Federal agencies do not have direct operational authority. Consequently, HHS has extensively solicited input from stakeholder groups and documented how input has or has not been incorporated, particularly in the initial plan document.	External stakeholders consistently report limited awareness of the scope and pace of the Action Plan, and how their efforts and interactions with individual HHS agencies fit into the larger initiative. A few external stakeholders, although generally satisfied that their input was solicited, perceived that their concerns were not being fully addressed. Several other stakeholder groups, including nurses, hospital housekeeping services, and medical device manufacturers, who could make specific contributions to the Action Plan were identified but have not yet been adequately engaged.
<p>Evaluation Summary: Despite the Action Plan’s extensive solicitation and documentation of stakeholder input, external stakeholders generally lack awareness of the scope of plan activities and how their efforts fit into the larger initiative, and a few perceive that their concerns have not been fully addressed. There are also several additional stakeholder groups that could potentially contribute to the Action Plan, but have yet to be adequately engaged.</p> <p>Recommendation: Reiterate the value of external stakeholders as partners to the Action Plan. Close the loop with stakeholder groups that provide input, to ensure understanding of how specific concerns have been addressed. Specify the explicit roles that different stakeholder groups can play in implementation of each element of the Action Plan. Conduct explicit outreach to the additional stakeholder groups identified, where resources permit.</p>		

Input Element	Strength	Opportunity
Incorporating the differing perspectives and interests of various stakeholders in the Action Plan	The Action Plan has established explicit goals to increase the adoption of evidence-based measures associated with HAI reductions. This simple, clear message is understandable and supported by most stakeholders.	Tensions exist among some elements of key stakeholder communities (including epidemiology, quality improvement, and consumer groups) regarding the adequacy of the available basic and applied sciences for defining effective HAI prevention strategies and for implementing those strategies. Furthermore, substantial tensions exist regarding how research and implementation resources should be spent. Analyses of competing options have been limited to date. Policymakers, health care administrators, providers, and consumers often have differing viewpoints.
<p>Evaluation Summary: As an initial statement, the clarity of the Action Plan's stated goals and targets was useful and generally well supported by stakeholders. However, underlying tensions among stakeholder groups related to differences in perspectives and interests may hinder progress of the Action Plan as the number and pace of activities being implemented increase.</p> <p>Recommendation: Allocate effort to understanding the tensions between various perspectives and interests related to HAI prevention, followed by efforts to build solutions that address or balance, rather than ignore, underlying tensions.</p>		

Input Element	Strength	Opportunity
Coordinating the breadth of programs and projects that constitute the Action Plan	As funding is allocated, programs and projects have been named and their goals have been widely disseminated.	The inventory, including naming and characterizing all Action Plan-related projects and programs, is only beginning. Agency inputs are needed to complete this task.
<p>Evaluation Summary: The Action Plan has described and disseminated information about funded programs and projects, but a systematic inventory is only beginning to be compiled.</p> <p>Recommendation: Move forward with the development of the Project and Program Inventory of Action Plan-related activities. As the inventory emerges, a more complete picture of the strengths and weaknesses of various individual programs and projects should be recognizable. This may prompt new efforts to fill strategic gaps, reduce redundancies, and ensure complementarities in Action Plan activities.</p>		

Input Element	Strength	Opportunity
Strategically assessing the value of potential programs to each other and existing Action Plan-related activities	Within a short period, multiple potential programs associated with the Action Plan have been identified. Multiple new projects have been funded. Certain agencies have implemented criteria for comparing the value of potential programs.	Limited progress has been made in applying criteria across agencies to compare potential progress in reducing HAIs. Also, the extent to which agencies take advantage of opportunities to supplement each other's strengths is only beginning to be examined.
<p>Evaluation Summary: The Evaluation Working Group and this evaluation should be working toward a more consistent approach to identifying criteria for comparing the effectiveness of potential programs within and across agencies. Underlying tensions, such as the relative value of short- and long-term goals associated with basic and clinical research –a s compared with community engaged and implementation research—should be considered.</p> <p>Recommendations: Move forward with the development of a Conceptual Model of the Action Plan, the Project and Program Inventory, and the Data Inventory. Use these as substrates to identify criteria for comparing potential programs within and across program areas.</p>		

Overall, we note that a large number of important efforts have been initiated, though the reasons why one particular project design was developed are often not clear. Whether strategies were selected because they provided the most promising approach to the achievement of goals or because of influential funding opportunities was not consistently clear. Information was not always available to indicate whether and which agencies and stakeholders favored which approaches. Information to indicate whether a selected program was superior to another was often not available. In many cases, evidence for the effectiveness of selected strategies was limited. In part, this has resulted from limited systematic data about HAI rates, infrastructure, research, and cost data, and variable specifications of metrics. Moreover, little information was available regarding the compatibility of one strategy with another.

Despite these limitations, extraordinary advances have been made by the Action Plan in a short time. This is apparent in the strengths associated with the Context evaluation and in the large number of strengths associated with the Input evaluation. Many of the areas noted by the IMPAQ/RAND team as opportunities have already been identified as priority areas by the Action Plan. As the September 2010 Stakeholder Meeting approaches, this is a critically important time to further implementation plans and to move forward with these areas.

Overall, the Context and Input evaluations have provided useful insights for the forthcoming Process and Product evaluations. These latter evaluations will, for the first time, allow enough of the moving pieces to be in place so that the Action Plan and its effectiveness can be evaluated as a whole. This Year 1 report, which presents our Context and Input evaluations and summarizes our data inventory, provides a sound foundation for the future phases of conducting this CIPP evaluation of the Action Plan.

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APPENDIX A: HHS AGENCY WEB SITE REVIEW

HHS Agency Web Site Review – Abstraction Form			
Agency Name: AHRQ		Home page URL: http://www.ahrq.gov/	
Does the Web site have a specific section dedicated to the Action Plan?		No, but there is a section for HAIs	
What is the intended audience for the Action Plan-related information?		<i>Action Plan Participants (e.g., Working Group members), non-HHS professionals, public. Mostly consumers</i>	
Do the Action Plan-related web pages link to the Web sites of other HHS agencies?		Yes: CDC, AHA, APIC, SHEA, IDSA, IHI, NIAID, HRET,	
Action Plan-related documents identified on the site:			
Document Name	URL	Topic: <ul style="list-style-type: none"> Historical context Policy context Description of pre-Action Plan initiatives/programs Action Plan development process Action Plan implementation and progress 	Brief description of document and its relevance to the Action Plan
AHRQ's Efforts to Prevent and Reduce Health Care-Associated Infections	http://www.ahrq.gov/qual/haiflyer.pdf	Action Plan implementation and progress	This fact sheet discusses why HAI are a cause for concern, AHRQ activities that support the reduction of HAIs, funding sources, and upcoming projects to reduce HAIs.
AHRQ's 2009 Funded Projects to Prevent Health Care-Associated Infections	http://www.ahrq.gov/qual/haify09.pdf	Action Plan implementation and progress	This fact sheet details the projects that AHRQ funded in FY 2009 to address various infections, including CLABSIs, MRSA, CDIs, SSIs, Carbapenem-resistant <i>Enterobacteriaceae</i> (CRE) infections, CAUTIs, and central line associated blood stream infections (CLABSIs)
Ending Health Care-Associated Infections	http://www.ahrq.gov/qual/haicusp.pdf	Action Plan implementation and progress	This fact sheet provides an overview of the projects AHRQ has supported since 2001 that have led to the successful reduction of CLABSIs in hospital intensive care units. In October 2009, AHRQ announced that the Comprehensive Unit-based Safety Program (CUSP) will expand to all 50 States and additional hospitals in States already participating in the program.

<i>Evidence Report/Technology Assessment</i> No. 9: Closing the Quality Gap: A Critical Analysis of Quality Improvement Strategies, Vol. 6 – Prevention of Healthcare-Associated Infections	http://www.aHRQ.gov/downloads/pub/evidence/pdf/qualgap6/hainfgap.pdf	Historical context	<p>The objective of this report, issued in 2007, is to determine the effects of quality improvement strategies on promoting adherence to interventions for prevention of SSIs, CLABSI, VAP, and CAUTIs and rates.</p>
2009 National Healthcare Quality Report	http://www.aHRQ.gov/qual/nhqr09/nhqr09.pdf	Action Plan implementation and progress/ Product evaluation	<p>This report discusses HAIs as well other health care issues and reports on progress and opportunities for improving health care quality. It includes measures and annual rates of improvement</p>
2009 National Healthcare Disparities Report	http://www.aHRQ.gov/qual/nhd09/nhdr09.pdf	Action Plan implementation and progress/ Product evaluation	<p>This report examines racial, ethnic, and socioeconomic disparities in quality of care and access to care. HAIs are included in this report.</p>

HHS Agency Web Site Review – Abstraction Form			
Agency Name: CDC		Home page URL: www.cdc.gov	
Does the Web site have a specific section dedicated to the Action Plan?		Yes/No Not exactly. The closest the CDC site comes to this is http://www.cdc.gov/ncidod/dhqp/stateHAplan.html	
What is the intended audience for the Action Plan-related information?		Action Plan Participants (e.g., Working Group members), non-HHS professionals, public: All of these groups	
Do the Action Plan-related web pages link to the Web sites of other HHS agencies?		Yes. OPHS.	
Action Plan-related documents identified on the site:			
Document Name	URL	Classification	Brief description of document and its relevance to the Action Plan
Template for State Healthcare-Associated Infections Plans	http://www.cdc.gov/ncidod/dhqp/pdf/StateHAIPlanningTemplate.pdf	Action Plan Implementation	Template for development of State plans. Important part of Action Plan implementation.
HAI: State Plans (presentation)	http://www.cdc.gov/ncidod/dhqp/hai/HAIStatePlan081909WebConference.pdf	Action Plan Implementation	Guidance for States in developing plans. Presentation from Web conference.
Overview: HA-MRSA	http://www.cdc.gov/ncidod/dhqp/ar_mrsa.html	Action Plan Development Process	Background on Action Plan-targeted infection
Overview: Clostridium Difficile Infections in Healthcare Settings	http://www.cdc.gov/ncidod/dhqp/id_Cdiff.html	Action Plan Development Process	Background on Action Plan-targeted infection
Prevention & Control: Catheter-Associated Urinary Tract Infections	http://www.cdc.gov/ncidod/dhqp/dpac_uti_pac.html	Action Plan Development Process	Background on Action Plan-targeted infection
Surgical Site Infection – FAQ	http://www.cdc.gov/ncidod/dhqp/FAQ_SSI.html	Action Plan Development Process	Background on Action Plan-targeted infection
Ventilator-Associated Pneumonia: Resources for Patients and Healthcare Providers	http://www.cdc.gov/ncidod/dhqp/dpac_ventilate.html	Action Plan Development Process	Background on Action Plan-targeted infection
First State-Specific Healthcare-	http://www.cdc.gov/hai/pdfs/stateplans/SIR_05_25_2010.pdf	Action Plan Implementation	Provides State-level data on CLABSI as

Associated Infections Summary Data Report			well as information on NHSN penetration. Intended (in part) to gauge progress on Action Plan.
Data and Statistics – NHSN	http://www.cdc.gov/nhsn/dataStat.html (web page with links to the following reports) http://www.cdc.gov/nhsn/PDFs/dataStat/2009NHSNReport.PDF http://www.cdc.gov/nhsn/PDFs/dataStat/2008NHSNReport.pdf http://www.cdc.gov/nhsn/PDFs/AR_report2008.pdf http://www.cdc.gov/nhsn/PDFs/dataStat/2006DialysisSurvReport.pdf http://www.cdc.gov/nhsn/PDFs/dataStat/2006NHSNreport.pdf http://www.cdc.gov/nhsn/PDFs/dataStat/NNIS_2004.pdf	Action Plan Development Process	National-level reports (most recent is 2009) based on NHSN data.
FAQs for each of the 6 HAIs	http://www.cdc.gov/ncidod/dhqp/HAI_shea_idsa.html (web page with links to the following documents) http://www.cdc.gov/ncidod/dhqp/pdf/guidelines/BSI_tagged.pdf http://www.cdc.gov/ncidod/dhqp/pdf/guidelines/CA-UTI_tagged.pdf http://www.cdc.gov/ncidod/dhqp/pdf/guidelines/Cdiff_tagged.pdf http://www.cdc.gov/ncidod/dhqp/pdf/guidelines/MRSA_tagged.pdf http://www.cdc.gov/ncidod/dhqp/pdf/guidelines/SSI_tagged.pdf http://www.cdc.gov/ncidod/dhqp/pdf/guidelines/VAP_tagged.pdf	Action Plan Development Process Action Plan Implementation	This page has FAQ documents for the 6 targeted HAIs based on SHEA/IDSA publications. All of these provided background/input for the Action Plan. Depending on when these were posted/developed, they may also be considered implementation since they're spreading information on the infections and prevention. Also, OPHS links to these documents.
Recovery Act: Funding by State	http://www.cdc.gov/HAI/recoveryact/map.html	Action Plan Implementation	Information on ARRA funding by State.
ABCs Surveillance Reports for MRSA	http://www.cdc.gov/abcs/reports-findings/surv-reports.html (this page contains the following reports) http://www.cdc.gov/abcs/reports-findings/survreports/mrsa08.html http://www.cdc.gov/abcs/reports-findings/survreports/mrsa07.html http://www.cdc.gov/abcs/reports-findings/survreports/mrsa06.html http://www.cdc.gov/abcs/reports-findings/survreports/mrsa05.html	Action Plan Development Process	ABCs is the main data source for MRSA in the Action Plan. These documents are national reports based on ABCs data.

	findings/surreports/mrsa05.html		
ABCs Information	http://www.cdc.gov/abc/index.html (ABCs Homepage) http://www.cdc.gov/abc/overview/background.html (Background on ABCs) http://www.cdc.gov/abc/downloads/ABCs_population_matrix_2009.pdf (surveillance populations - ABCs conducts surveillance for MRSA in 9 metropolitan areas) http://www.cdc.gov/abc/downloads/MRSA_case_report_form_2009.pdf (MRSA case report form) http://www.cdc.gov/abc/methodology/case-definition-ascertain.html (case definitions and ascertainment) http://www.cdc.gov/abc/methodology/lab-characterization.html (laboratory characterization) http://www.cdc.gov/abc/methodology/surveillance-evaluation.html (surveillance evaluation)	Action Plan Development Process	ABCs is one of the data sources for the metrics in the Action Plan. These pages contain detailed information on the ABCs system. Considerable technical information is included. Background for Action Plan development.
NHSN	http://www.cdc.gov/nhsn/PDFs/pscManual/4_PSC_CLABSCurrent.pdf (CLABSI reporting instructions) http://www.cdc.gov/nhsn/PDFs/pscManual/5_psc_CLIPcurrent.pdf (CLIP adherence reporting instructions) http://www.cdc.gov/nhsn/pdfs/pscManual/7pscCAUTICurrent.pdf (CAUTI reporting instructions) http://www.cdc.gov/nhsn/PDFs/pscManual/6_pscVAPcurrent.pdf (VAP reporting instructions) http://www.cdc.gov/nhsn/PDFs/pscManual/14_Tables_of_Instructions.pdf (table of instructions for the many NHSN data collection protocols) http://www.cdc.gov/nhsn/forms/57.125_CLIP_BLANK.pdf (CLIP data collection form) http://www.cdc.gov/nhsn/forms/57.114_UTI_BLANK.pdf (UTI data collection form) http://www.cdc.gov/nhsn/forms/57.111_PNEU_BLANK.pdf (pneumonia data collection form) http://www.cdc.gov/nhsn/forms/57.108_PrimaryBSI_BLANK.pdf (blood stream infection data collection form) http://www.cdc.gov/nhsn/PDFs/Overview_MRSA_Surveillance_Final12_08.pdf (MRSA surveillance available using NHSN) http://www.cdc.gov/nhsn/PDFs/pscManual/12pscMDRO_CDADcurrent.pdf (MRSA and C. diff. reporting instructions)	Action Plan Development Process	The Patient Safety Component is the part of NHSN that captures many metrics listed in the Action Plan. Much technical information is included.

	http://www.cdc.gov/nhsn/forms/57.128_LabIDEvent_BLANK.pdf (laboratory-identified MDRO infection data collection form) http://www.cdc.gov/nhsn/forms/57.127_MDRMonthlyReporting_BLANK.pdf (MDRO prevention process data collection form)		
ARRA: Resources for State Partners	http://www.cdc.gov/HAI/recoveryact/stateResources/stateResources.html (page with links to the following resources) http://www.cdc.gov/hai/ppt/CollaborationCookbook(Cleared2-19-2010)revaym.ppt (collaboration toolkit) http://www.cdc.gov/HAI/pdfs/toolkits/CAUTItoolkit_3_10.pdf (CAUTI toolkit) http://www.cdc.gov/HAI/ppt/CAUTItoolkit_revised_final3_10.ppt (CAUTI toolkit presentation) http://www.cdc.gov/HAI/recoveryact/PDF/CAUTI_EvalQuestions_Final_Clearedversion32910.pdf (CAUTI baseline practices assessment tool) http://www.cdc.gov/hai/pdfs/toolkits/CDItoolkitwhite_clearance_edits.pdf (C. diff. toolkit) http://www.cdc.gov/hai/ppt/CDItoolkit3242010.pptx (C. diff. toolkit presentation) http://www.cdc.gov/HAI/recoveryact/PDF/CDI_EvalQuestions_Final_Clearedversion32910.pdf (C. diff. baseline practices assessment tool) http://www.cdc.gov/hai/pdfs/toolkits/CLABSItoolkit_white020910_final.pdf (CLABSI toolkit) http://www.cdc.gov/hai/ppt/CLABSItoolkit3242010.ppt (CLABSI toolkit presentation) http://www.cdc.gov/HAI/recoveryact/PDF/CLABSI_EvalQuestions_Final.pdf (CLABSI baseline practices assessment tool) http://www.cdc.gov/hai/pdfs/toolkits/MRSA_toolkit_white_020910_v2.pdf (MRSA toolkit) http://www.cdc.gov/hai/ppt/MRSA_toolkit03242010.ppt (MRSA toolkit presentation) http://www.cdc.gov/HAI/recoveryact/PDF/MRSA_EvalQuestions_Final_Clearedversion32910.pdf (MRSA baseline practices assessment tool) http://www.cdc.gov/HAI/pdfs/toolkits/SSI_toolkit021710SIBT_revised.pdf (SSI toolkit) http://www.cdc.gov/HAI/ppt/SSItoolkit03242010.pptx (SSI toolkit presentation) http://www.cdc.gov/HAI/recoveryact/PDF/SSI_EvalQuestions_Final.pdf (SSI baseline practices assessment tool)	Action Plan Implementation	There is a collaboration toolkit as well as toolkits and assessment tools for 5 of the targeted infections (not VAP) that give background on infection, prevention techniques, metrics, etc.
State Plans - HAI	http://www.cdc.gov/HAI/HAIStatePlans.html	Action Plan Implementation	This page has pdf versions of each State

			plan to address HAIs.
Infection Control Guidelines	http://www.cdc.gov/hicpac/pubs.html (this page contains the links that follow) http://www.cdc.gov/mmwr/PDF/rr/rr5116.pdf (hand hygiene) http://www.cdc.gov/hicpac/pdf/CAUTI/CAUTI_guideline2009final.pdf (CAUTI prevention) http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5110a1.htm (CLABSI prevention) http://www.cdc.gov/ncidod/dhqp/pdf/guidelines/SSI.pdf (SSI prevention) http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5303a1.htm (pneumonia prevention) http://www.cdc.gov/hicpac/pdf/guidelines/MDROGuideline2006.pdf (MDRO prevention)	Action Plan Development Process AND Action Plan Implementation	HICPAC's prevention guidelines relevant to the Action Plan
Guidance on Public Reporting of Healthcare-Associated Infections: Recommendations	http://www.cdc.gov/hicpac/pdf/guidelines/PublicReportingGuide.pdf	Action Plan Development Process	HICPAC's recommendations regarding reporting of HAIs. Background for Action Plan.

HHS Agency Web Site Review – Abstraction Form			
Agency Name: CMS		Home page URL: www.cms.gov	
Does the Web site have a specific section dedicated to the Action Plan?		No	
What is the intended audience for the Action Plan-related information?		There is very little information directly related to the Action Plan. The information on the site is mostly related to ongoing efforts described in the Oversight and Incentives chapter of the Action Plan that the plan indicates has sections on, can be adapted to accommodate, the HAls from the plan or infection control more generally. The information is therefore for medical facilities (e.g., hospitals, ambulatory centers, etc.) or other parties that need to know specifics of the different programs.	
Does the Action Plan-related web pages link to the Web sites of other HHS agencies?		No, although there are external links related to their programs.	
Action Plan-related Documents identified on the site:			
Document Name	URL	Category	Brief description of document and its relevance to the Action Plan
Conditions of Participation – Infection Control (42 CFR); Hospitals	http://edocket.access.gpo.gov/cfr_2004/octqtr/pdf/42cfr482.42.pdf	Description of pre-Action Plan initiatives/programs	The Federal health and safety requirements that hospitals and other providers must meet to participate in the Medicare and Medicaid programs. The CoPs are intended to ensure that high quality care is provided to all patients. Compliance with the CoPs is determined by State Survey Agencies (SAs) or Accreditation Organizations (AOs). Cited in the Action Plan as part of regulatory oversight.
State Operations Manual (Link to page with documents including 9 chapters, exhibits, appendices)	http://www.cms.gov/SurveyCertificationGenInfo/01_Overview.asp#TopOfPage	Description of pre-Action Plan initiatives/programs	The State Operations Manual is the manual for State Survey Agencies to conduct the certification process. The appendix contains the interpretive guidelines for how CMS, through the SA surveyors, enforces regulatory requirements, including those associated with infection control. The interpretive guidelines for infection control were updated to reflect changing infectious and communicable disease threats as well as

			current and nationally recognized infection control guidelines, best practices, and other resources for hospitals. The certification process and interpretive guidelines are cited in the Action Plan as part of regulatory oversight under Survey and Certification.
Link to overview of Prospective Payment System overview and related links	http://www.cms.gov/ProspMedicareFeeSvcPmtGen/	Description of pre-Action Plan initiatives/programs	Describes Medicare's methods of reimbursement. Cited in the Hospital Acquired Condition and Present on Admission Indicator Reporting section of the Action Plan, part of the Value-Based Purchasing section.
Paper based on Listening Sessions regarding Value-Based Purchasing	http://www.cms.gov/AcuteInpatientPPS/Downloads/Hospital_VBP_Plan_Issues_Paper.pdf	Description of pre-Action Plan initiatives/programs	Value-Based Purchasing is cited in the Action Plan as a method for financial incentives.
Plan to Congress to implement Value-Based Purchasing	http://www.cms.gov/AcuteInpatientPPS/downloads/HospitalVBPPlanRTCFINALSUBMITTED2007.pdf	Description of pre-Action Plan initiatives/programs	This document is the plan presented to Congress for implementing Value-Based Purchasing. VBP is cited in the Action Plan as a method for financial incentives.
Slide Presentations from First Listening Session on Value-Based Purchasing	http://www.cms.gov/AcuteInpatientPPS/downloads/ls_powerpoints_011707.zip	Description of pre-Action Plan initiatives/programs	Several slide decks that were used in the first listening session on Value-Based Purchasing. VBP is cited in the Action Plan as a method for financial incentives.
Slide presentations from Second Listening Session on Value-Based Purchasing	http://www.cms.gov/AcuteInpatientPPS/downloads/LS2slides.zip	Description of pre-Action Plan initiatives/programs	Several slide decks that were used in the first listening session on Value-Based Purchasing. VBP is cited in the Action Plan as a method for financial incentives.
Issues Paper from First Listening Session on Value-Based Purchasing	http://www.cms.gov/AcuteInpatientPPS/downloads/hospital_VBP_plan_issues_paper.pdf	Description of pre-Action Plan initiatives/programs	Paper includes process for developing the VBP plan, goals, design issues, and areas in which CMS is seeking input. VBP is cited in the Action Plan as a method for financial incentives.
Options Paper from Second Listening Session on Value-Based Purchasing	http://www.cms.gov/AcuteInpatientPPS/downloads/HospitalVBPOptions.p	Description of pre-Action Plan initiatives/programs	Paper describes VBP options, including goals, design issues, performance assessment model, incentive payment

	df		structure options, measures, data, and reporting issues. VBP is cited in the Action Plan as a method for financial incentives.
Roadmap for implementing Value-Based Purchasing	http://www.cms.gov/QualityInitiativesGenInfo/downloads/VBPRoadmap_OEA_1-16_508.pdf	Description of pre-Action Plan initiatives/programs	VBP is cited in the Action Plan as a method for financial incentives.
Link to Hospital-Acquired Conditions (Present on Admission Indicator) (HAC POA)	http://www.cms.gov/HospitalAcqCond/	Description of pre-Action Plan initiatives/ programs	Web site link to CMS page on HAC POA, includes overview and further links to information including regulations, reporting, coding, reporting affected hospitals. HAC POA is cited in the Action Plan as a method for financial incentives, part of Value-Based Purchasing. Some of the HACs are HAIs.
Fact Sheet on HAC POA	http://www.cms.gov/HospitalAcqCond/downloads/HAC_Factsheet.pdf	Description of pre-Action Plan initiatives/programs	Fact sheet describing HAC POA. HAC POA is cited in the Action Plan as a method for financial incentives, part of Value-Based Purchasing. Some of the HACs are HAIs.
Federal Register Notice about HAC POA Listening session	http://www.cms.gov/HospitalAcqCond/Downloads/1422_N_FEDERAL_REGISTER_VERSION_PUB_10_30_08_508.pdf	Description of pre-Action Plan initiatives/ programs	FR notice announcing listening session. HAC POA is cited in the Action Plan as a method for financial incentives, part of Value-Based Purchasing. Some of the HACs are HAIs.
HAC POA Listening Session Transcript	http://www.cms.gov/HospitalAcqCond/Downloads/HAC_Listening_Session_12-18-2008_Transcript.pdf	Description of pre-Action Plan initiatives/ programs	Transcript of listening session including presentation by many at CMS, CDC, and others. HAC POA is cited in the Action Plan as a method for financial incentives, part of Value-Based Purchasing. Some of the HACs are HAIs.
Hospital Quality Measures Initiatives Overview	http://www.cms.gov/HospitalQualityInits/	Description of pre-Action Plan initiatives/ programs	Overview of Hospital Quality Initiatives
Hospital Compare Web site	http://www.hospitalcompare.hhs.gov/hospital-search.aspx?AspxAutoDetectCookieSupport=1	Description of pre-Action Plan initiatives/ programs	The Web site, which is populated by RHQDAPU, was created in a partnership between CMS and the Hospital Quality Alliance (HQA) to provide hospital quality information to

			consumers.
Hospital Compare archived information on CMS site	http://www.cms.gov/HospitalQuality/nits/11_HospitalCompare.asp#TopOfPage	Description of pre-Action Plan initiatives/ programs	The link from the CMS site to archived information from Hospital Compare. Referenced in the Action Plan as related to transparency.
Text of Section 501(b) of the Medicare Prescription Drug, Improvement and Modernization Act (MMA) 2003	http://www.cms.gov/HospitalQuality/nits/downloads/HospitalMMASection501b.pdf	Description of pre-Action Plan initiatives/ programs	Text of the section of the MMA law related to RHQDAPU (Reporting Hospital Quality Data For Annual Payment Update) measures used to populate Hospital Compare. The Web site is discussed in the Action Plan as related to transparency.
Text of Title V, Subtitle A, Section 5001(a) of the Deficit Reduction Act of 2005	http://www.cms.gov/HospitalQuality/nits/downloads/HospitalDRASection501a.pdf	Description of pre-Action Plan initiatives/ programs	Text of the section of the Deficit Reduction Act of 2005, law related to RHQDAPU (Reporting Hospital Quality Data For Annual Payment Update) measures used to populate Hospital Compare. The Web site is discussed in the Action Plan as related to transparency.
National Summary statistics from RHQDAPU from Hospital Compare	http://www.cms.gov/HospitalQuality/nits/downloads/HospitalNationalLevelPerformance.pdf	Description of pre-Action Plan initiatives/ programs	A document with summary statistics from the Hospital Compare Web site. Hospital Compare provides data to consumers about hospital performance from RHQDAPU. Includes pneumonia and SCIP measures. It is described in the Action Plan as related to transparency.
Overview of Specifications of Measures Displayed on Hospital Compare	http://www.cms.gov/HospitalQuality/nits/downloads/HospitalOverviewOfSpecs200512.pdf	Description of pre-Action Plan initiatives/ programs	Document describes the specifications for measures on the Hospital Compare Web site. Hospital Compare and the RHQDAPU measures that populate it are described in the Action Plan as related to transparency. Includes pneumonia and SCIP measures.
Quality Improvement Organization 9th Statement of Work (2008) and fact sheet	http://www.cms.gov/QualityImprovementOrgs/downloads/9thSOWBaseContract_C_08-01-2008_2_.pdf	Description of pre-Action Plan initiatives/ programs	CMS contracts with one organization in each state, to serve as a Quality Improvement Organization (QIO) contractor. QIOs are staffed by professionals

	http://www.cms.gov/QualityImprovementOrgs/downloads/9thSOWAnnouncement080508.pdf (Fact Sheet)		trained to review medical care, to help beneficiaries with complaints about the quality of care and to implement improvements in the quality of care available throughout the spectrum of care. This is the 9th SOW (3 years), referenced in the Action Plan, and includes collaboration to combat MRSA.
Link to Premier Hospital Quality Incentive Demonstration and related documents	http://www.cms.gov/HospitalQualityInits/35_HospitalPremier.asp http://www.cms.gov/HospitalQualityInits/downloads/HospitalPremierFactSheet200907.pdf (Fact sheet) http://www.cms.gov/HospitalQualityInits/downloads/HospitalParticipatelists.pdf (participating hospitals) http://www.cms.gov/HospitalQualityInits/downloads/HospitalPremierCal200512.pdf (calculation of incentives)	Description of pre-Action Plan initiatives/ programs	Part of CMS's page dealing with the Premier Hospital Quality Incentive Demonstration. Has various links to fact sheets, participating hospitals, performance information, and calculations of incentives. One of the programs cited in the Action Plan as a demonstration aimed at improving the value of health care.
Link to Medicare Acute Care Episode Demonstration and related documents	http://www.cms.gov/DemoProjectsEvalRpts/MD/itemdetail.asp?filterType=none&filterByDID=-99&sortByDID=3&sortOrder=descending&itemID=CMS1204388&intNumPerPage=10 http://www.cms.gov/DemoProjectsE	Description of pre-Action Plan initiatives/ programs	Part of CMS's page dealing with the Medicare Acute Care Episode (ACE) Demonstration. Has various links to fact sheets, guidance, technical specifications, gain sharing rules, etc. One of the programs cited in the Action Plan as a demonstration aimed at improving the value of health care

	valRpts/downloads/ACEFactSheet.pdf (fact sheet) http://www.cms.gov/DemoProjectsE valRpts/downloads/ACETechSpecAQ M.pdf (technical specifications) http://www.cms.gov/DemoProjectsE valRpts/downloads/Applicant_Teleco nference.pdf (applicant teleconference presentation)		
Medicare Advantage Part C Reporting Requirements and related links/documents	http://www.cms.gov/HealthPlansGenInfo/16_ReportingRequirements.asp	Description of pre-Action Plan initiatives/ programs	Describes reporting requirements for Medicare Advantage Part C, one of the HAI-related initiatives mentioned in the Action Plan. Some of the measures are HAI-related.
State Medicaid Directors Letter regarding HACs	http://www.cms.gov/SMDL/downloads/SMD073108.pdf	Description of pre-Action Plan initiatives/ programs	Letter cited in the Action Plan to State Medicaid Directors about State amendments to HAC non-payment policy. CMS expects that the majority of States will move to align their Medicaid payment policies with the Medicare HAC policy. Given that many of the HACs deal with hospital-acquired infections, this alignment of Medicare and Medicaid payment policy will send a strong, consistent message to hospitals
Medicaid Transformational Grants Fact Sheet and Web site link	http://www.cms.gov/MedicaidTransGrants/02_2007awards.asp http://www.cms.gov/MedicaidTransGrants/Downloads/Medicaid_Transformation_Grants_FactSheet.pdf (fact	Description of pre-Action Plan initiatives/ programs	Overview of Transformational Grants, including Neonatal Outcomes Project referenced in Action Plan under other HAI-related initiatives.

	sheet)		
Ambulatory Surgical Centers HAI reduction effort press release	http://www.cms.gov/apps/media/press/release.asp?Content=3479&intNumPerPage=10&checkDate=&checkKey=&srchType=1&numDays=3500&srchOpt=0&srchData=&keywordType=All&chkNewsType=1%2C+2%2C+3%2C+4%2C+5&intPage=&showAll=&pYear=&year=&desc=&callbackOrder=date http://www.cms.gov/SurveyCertificationGenInfo/Downloads/ASC_HAI_MAP.pdf (Map and fact sheet)	Action Plan implementation	Describes ARRA funding for 12 States to reduce HAIs in ambulatory surgical centers. Links to OPHS Action Plan site. (Only link found on CMS site to plan.)

HHS Agency Web Site Review – Abstraction Form			
Agency Name: OPHS		Home page URL: http://www.hhs.gov/ash/	
Does the Web site have a specific section dedicated to the Action Plan?		Yes http://www.hhs.gov/ophs/initiatives/hai/index.html	
What is the intended audience for the Action Plan-related information?		Policymakers	
Does the Action Plan-related web pages link to the Web sites of other HHS agencies?		Yes: AHRQ, CDC. (Other agencies: SHEA, IDSA)	
Action Plan-related documents identified on the site:			
Document Name	URL	Topic: <ul style="list-style-type: none"> • Historical context • Policy context • Description of pre-Action Plan initiatives/programs • Action Plan development process • Action Plan implementation and progress 	Brief description of document and its relevance to the Action Plan
Presentation: Healthcare-Associated Infections: State Plans	http://www.hhs.gov/ophs/initiatives/hai/haistateplan081909webconference.ppt	<ul style="list-style-type: none"> • Action Plan implementation and progress 	A presentation to provide guidance to States in developing State Action Plans to prevent HAIs (part of the Action Plan implementation).
Presentation: HHS Efforts to Prevent Healthcare-Associated Infections	http://www.hhs.gov/ophs/initiatives/hai/meetings/psemtg06302009.ppt	<ul style="list-style-type: none"> • Action Plan development process 	Presentation by the chairs of Action Plan Working Groups on the outcome of the stakeholder meetings (part of Action Plan development).
Reducing Healthcare-Associated Infections: Report on Stakeholder Meetings	http://www.hhs.gov/ophs/initiatives/hai/meetings/hai_gen_stake_mtg.pdf	<ul style="list-style-type: none"> • Action Plan development process 	Summary of the input from stakeholders in the design/revision of the Action Plan.
HHS Response to the Report on General Stakeholder	http://www.hhs.gov/ophs/initiatives/hai/meetings/	<ul style="list-style-type: none"> • Action Plan implementation and progress 	Short document, cover letter for the Stakeholder Meetings report. Also describes other Action Plan activities.

Meetings	hhs_keystone.pdf		
2009 Healthcare-Associated Infections Information Technology Meetings	http://www.hhs.gov/ophs/initiatives/hai_mtgs/hai_mtgs_summary.pdf	<ul style="list-style-type: none"> Action Plan development process 	Summary of meetings with health IT stakeholders about the infrastructure and personnel needs for gathering data to carry out the goals of the Action Plan.
HHS Response to IT Stakeholder Meeting Report	http://www.hhs.gov/ophs/initiatives/hai_mtgs/it_report.pdf	<ul style="list-style-type: none"> Action Plan implementation and progress 	Short document, cover letter for the IT Meetings report. Also describes other Action Plan activities.

APPENDIX B: INTERVIEW PROTOCOL

Sample Interview Questions for Context and Input Evaluations

Examples of questions we asked interviewees are listed below. Not every interviewee was asked every question. Additionally, the discussion guides were tailored to the stakeholder type (Federal agencies, State agencies, health care providers, quality improvement and accrediting organizations, purchasers and insurers, academic/ research institutions, and consumers). Examples of tailored questions for the different stakeholder groups are provided at the end of this Appendix.

Antecedent Events and Historical Context

1. When did HAIs become recognized by policy makers and the American public as an important issue?
2. What were the key drivers/events that moved HAIs to the forefront of the policy agenda?
3. Prior to HAIs moving to prominence as a patient safety issue, how would you characterize the types and extent of HAI policies and activities at the federal, state, and private-sector level (including HAI prevention, surveillance, and treatment)?
4. Once HAIs became a visible public issue, how did federal agencies and Congress respond?

Development of the Action Plan

5. From your perspective, what do you think were the major catalysts that led to the Action Plan? What were the main events, timeline? Who were the main players?
6. How were you and/or your organization involved in the development of the Action Plan?
7. What critical documents—either governmental and private reports or key journal articles—were used to develop the Action Plan? Are there any key documents that have resulted from the Action Plan (such as white papers, agency action plans)?

Current Role in Action Plan Activities

8. What is your organization's current role in the Action Plan? What parts of your organization are most responsible and involved in Action Plan activities?
9. Has your organization changed its strategies for addressing HAIs as a result of its involvement in the Action Plan? If so, in what ways (e.g., broader or narrower focus, target different stakeholder groups, etc)?
10. Has your organization received any new funding to work on HAI issues, either as part of the American Recovery and Reinvestment Act (ARRA) or other federal funding streams?

Current Status and Context of the Action Plan

11. The Action Plan specifies 5-year target goals for prevention of six categories of healthcare-associated infections (central line-associated bloodstream infections, *Clostridium difficile* infections, catheter-associated urinary tract infections, MRSA infections, surgical site infections, and ventilator-associated pneumonia).
 - In your opinion, are these six HAIs the ones that the Action Plan should be focusing on?
 - Are the prevention targets specified in the Action Plan appropriate and realistic?
 - Are there particular HAIs for which you think there are insufficient prevention practices or evidence for those practices?
12. What stakeholder organizations or groups have been most significantly involved in the Action Plan initiative? These could include other federal agencies, state agencies, as well as various private non-governmental stakeholders. Why are these particular stakeholders important? What are their roles in reducing HAIs?
13. What have been the major challenges in implementing the Action Plan so far?
14. What would you consider have been the major achievements or milestones in implementing the Action Plan so far?
15. What infrastructure currently exists for implementation and dissemination of the information and HAI prevention practices? What additional infrastructure is needed to carry out the Action Plan?

Opportunities and Challenges for Preventing and Reducing HAIs

16. What do you see as the strengths and weaknesses of the current Action Plan in being able to reduce HAI rates nationally?
17. What topics do you see as being high priority research areas for strengthening the evidence base about *the causes of HAIs*?
18. Are there any research areas on causes of HAIs that you feel are currently being neglected or underemphasized in the Action Plan? If so, please describe them.
19. Data systems able to measure the occurrence of healthcare-associated infections and monitor rates of HAIs are a key emphasis in the Action Plan.
 - What would you say are the main strengths and weaknesses of current data systems or measures to monitor HAI rates? (e.g., interoperability, gaps in geography, HAI coverage, care settings, lack of valid measures).
20. What information about HAI prevention and infection rates that is not currently available would be most useful to have?
21. The Action Plan currently includes a task for inventorying and comparing the various national databases on HAI presently available.

22. What would you see as the most important goals or value-added of such an inventory? (e.g., having everything in one place, documenting compatibility issues across data sets, knowing how to access different data sources)

Future Directions

23. What are your hopes and aspirations for what the Action Plan and all of its related activities will accomplish?
24. What strategies do you see as essential to increasing the effectiveness of the Action Plan?

Other Contacts

25. Who else would you recommend we speak to within your organization in terms of policies and activities related to healthcare-associated infections?
26. Who else might have expertise in particular with HAI data systems and measures?
27. Who else within private stakeholder organizations would you recommend we talk to (e.g., consumer groups, health insurers, hospital, physician, or other health provider associations)?

Examples of Tailored Questions by Stakeholder Group

Federal Agencies

For HHS interviewees whose agency is leading an Action Plan working group:

1. What is your role in the working group?
2. What is involved in being the lead agency for that group?
3. What are the goals of the working group's activities?
4. Are you measuring whether you are achieving these goals? If so, how are you measuring these goals?
5. Are there any other organizations (either within or outside the federal government) your agency collaborates with on the activities of your working group? If yes, what are they?
6. How effective have the FAWG agencies been at working together to implement the Action Plan?
7. What are your expectations of how interagency coordination will change in the future?
8. Is there anything that might improve the ability of agencies to work together to implement the Action Plan?

State Agencies

1. To what extent was your agency, or you, aware of the development of the federal HHS Action Plan? Did you or your agency have any involvement? If so, what was this role? Do you know if other state agencies have been involved?
2. Has your organization received any new funding to work on HAI issues, either as part of the American Recovery and Reinvestment Act (ARRA) or other federal funding streams?
 - a. If yes, please describe those projects (e.g., goals, activities).
 - b. How critical was this funding to your agency being able to work on HAI-related activities?
3. As you may be aware, Congress enacted the Omnibus Appropriations Act; this law mandates all states must submit a plan to reduce HAIs by January 1, 2010 if they currently receive a Preventive Health and Health Services Block Grant. Are you aware of this mandate?
 - a. Was your agency involved in developing the Action Plan for your state?
 - b. If yes, please describe what is proposed in that plan..
 - c. What impact do you think your state's plan will have on preventing HAIs?
 - d. Is the impact of your state's plan being evaluated? If so, how is it being evaluated (e.g., what measures are being used to evaluate the plan's impact, what time period is the evaluation covering)?
4. How has having to develop the state Action Plan changed or impacted the response to HAIs within your state? How about in other states you may be aware of?
5. What have been the roles of state-level insurers in particular? Which insurers have been the most active or innovative, and what are they doing?
6. In general, which states that you're aware of have the most active or innovative sets of HAI activities? What things are going on in these states? How do the amount of collaboration and the roles that different stakeholders play vary across states?
7. To your knowledge, what roles have the regional HHS offices (e.g., the HHS' Regional Health Administrators, CDC regional public health advisors, CMS' regional offices) played in coordinating HAI activities within and across states?
8. Are you aware of state-level data reporting efforts on HAIs in [fill in state]? Can you describe what kind of data is being tracked and how it is being used? Are these reporting efforts part of the State Action Plan in any way?

Health Care Provider, Quality Improvement, and Accrediting Organizations

1. Thinking about the various public reporting systems for information on the quality and safety of hospital and health care providers, do you think the information made available on infections in particular has influenced consumers' behavior?
 - a. If so, please describe scope.
 - b. What kind of impact has it had on hospitals or providers' efforts to improve quality and safety?
 - c. Does your organization have a current role in the HHS Action Plan activities, such as implementing any part of the Action Plan recommendations, partnering or giving advice in any way to federal agencies or others involved with the Action Plan, etc.?
 - d. If yes, please describe those activities.
 - e. What parts of your organization are most responsible and involved in Action Plan activities?
 - f. Where do HAI issues and the Action Plan fall within the range of your organization's priorities?
 - g. What are the implications of the Action Plan or Action Plan-related activities for health care providers?
 - h. What are the implications of the Action Plan or Action Plan-related activities for health care improvement organizations, including accreditation organizations?

Purchasers and Insurers

1. As you may know, the Action Plan highlights various regulatory, financial, and public transparency tools and incentives for reducing national rates of HAIs. The recommended actions center on coordinated action between CMS, accreditors, and industry groups to incorporate incentives for preventing HAIs into Medicare Conditions of Participation, Joint Commission and other certification standards; to establish of hospital pay-for-reporting and other public reporting mechanisms; and to implement value-based purchasing incentives and requirements.
 - a. From your perspective, what are the most important priorities among these regulatory oversight and financial incentives for CMS and other federal agencies participating in the Action Plan to focus on?
 - b. In your assessment, to what extent do these various initiatives currently affect, or have the potential to affect, the policies and practices of private sector insurers and payers?

Academic/Research Institutions

1. What are the primary ways that you see research about HAI prevention being disseminated?
 - a. How effective are these dissemination methods?
 - b. Is the information reaching the people it needs to reach?
 - c. How could information about HAI prevention be disseminated more effectively?
2. What are some of the key issues currently being considered by researchers around the topic of HAI? What are the “hot topics” in HAI research and prevention work?
3. In developing the Action Plan, the Research Working Group started by considering a long list of HAIs, and through a process of debate and public comment, the list of HAIs was narrowed to focus on these six categories of healthcare-associated infections: central line-associated bloodstream infections, *Clostridium difficile* infections, catheter-associated urinary tract infections, MRSA infections, surgical site infections, and ventilator-associated pneumonia.
 - a. In your opinion, are these six HAIs the ones that the Action Plan should be focusing on?
 - b. Are the prevention targets specified in the Action Plan appropriate and realistic?
 - c. Do practices exist to prevent these types of HAIs, and what is the strength of the evidence behind those practices?
 - d. What research questions are most critical related to these HAIs and their prevention according to the goals of the Action Plan?
 - e. Are there other HAIs that you think should be included as a primary focus area for the Action Plan? If so, what are those HAIs? Why do you feel they should be given higher priority?
4. Have you made any changes to the focus of your research on addressing HAIs as a result of the implementation of the Action Plan? If so, in what ways (broader or narrower focus, focus on different type of HAI, etc.)?

Consumers

1. What are some of the key HAI issues or implications from the perspective of consumers and consumer organizations?
2. What do you see as the biggest implications of the Action Plan or Action Plan-related activities for consumers or consumer organizations?
3. What role in reducing national rates of HAIs is it reasonable or feasible to expect individual consumers to play? For consumer organizations?

APPENDIX C: LETTER FROM DONALD WRIGHT, MD, MPH



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Assistant Secretary for Health
Office of Public Health and Science
Washington D.C. 20201

March 2010

I am writing to encourage you to participate in an important comprehensive evaluation of the U.S. Department of Health and Human Services (HHS) Action Plan to Prevent Healthcare-Associated Infections.

As you may know, the Action Plan represents a potential model for how federal agencies can work together with stakeholders to address significant public health and healthcare improvement issues. Your input would help provide critical guidance to the strategies and activities of this initiative.

Your participation in the evaluation would consist of a 1-hour interview to obtain your perspective on what the priorities of the Action Plan should be, the progress being made on healthcare-associated infection issues, and what would be required of the Action Plan to meet its goals.

HHS has selected IMPAQ International and the RAND Corporation to conduct this evaluation. IMPAQ International is a social science and policy research firm based in Columbia, Maryland. The RAND Corporation is an independent policy research organization, whose Health division is one of the largest private health research groups in the world. Both have extensive experience conducting comprehensive national healthcare evaluations.

The IMPAQ/RAND team will conduct the evaluation independently of HHS and maintain the confidentiality of all participants. Information gathered through the interviews will not be reported in any way that can be attributed to individual participants or their affiliated organizations without their permission. HHS will also not be told who has or has not participated in the evaluation.

Again, we urge you to participate in this important evaluation. Our ability to understand and incorporate the perspectives of the full range of stakeholders in healthcare-associated infection issues is necessary to ensure that the Action Plan can fulfill its objective of significantly reducing rates of healthcare-associated infections over the next 5 years.

If you have any questions regarding the Action Plan or this evaluation, please do not hesitate to contact Ms. Rani Jeeva in the Office of Public Health and Science, Office of Healthcare Quality at Rani.Jeeva@hhs.gov or at 202-205-5245.

Sincerely,

A handwritten signature in black ink, reading "Don Wright MD MPH".

Don Wright, MD, MPH
Deputy Assistant Secretary for Healthcare Quality

U.S. Public Health Service

APPENDIX D: SUMMARY OF THE DATA INVENTORY INTERIM REPORT'S FINDINGS

Baseline Rates

As part of this evaluation, the IMPAQ/RAND team has been charged with recommending a set of baseline measures for the surveillance and tracking of national rates of HAIs. These recommendations are based on the product evaluation activities undertaken in Year 1. Our recommendations have been guided by the principles of triangulation, recognizing that no single data source is capable of providing a fully accurate or complete assessment of HAIs in the United States. These recommendations are supported in the companion IMPAQ/RAND report titled Report to AHRQ on Baseline Measures, Inventory, and Recommendations.¹¹

Our specific recommendations include:

- As a first step, data from all available HHS data sources, except for the National Health and Nutrition Examination Survey (NHANES), should be used to examine baseline national and State HAI rates. The only exception is NHANES, because it collects data on MRSA carriage rather than on MRSA infections, and the data therefore do not provide information on healthcare-associated infections. Furthermore, the NHANES MRSA data exist only for the period 2001–2004.
- Using all the remaining HHS data sources—including the National Healthcare Safety Network (NHSN), Hospital Compare, the Active Bacterial Core Surveillance (ABCs), the Medicare Patient Safety Monitoring System (MPSMS), and the Healthcare Cost and Utilization Project (HCUP)—will result in as comprehensive a baseline as possible and will provide information for the triangulation procedures outlined below.
- State-level information on HAI and prevention process adherence rates will also be useful since many of the HAI prevention initiatives associated with the Action Plan are State-based. The data systems profiled in the inventory vary in their capabilities for rate generation at the State level. Potential sources for State-level data include NHSN, ABCs, Hospital Compare, MPSMS, and HCUP.

Triangulation of Rates

After compiling rates, and whenever rates can be derived from multiple sources, the IMPAQ/RAND evaluation team recommends:

- A systematic comparison and analysis of the rates should be conducted in light of the foregoing analysis, to better understand the effects of different surveillance definitions, data collection methods, and sample features. This is consistent with the Action Plan's recommendation noting the need for "cross-walking" among data systems that use direct patient observation, laboratory data, and administrative data.⁶

- For all six infection types, rates can and should be generated using data from multiple sources (which will only exclude four metrics for which there is only one data source). Recommended comparisons across data systems are shown in **Exhibit 16**, where cells with check marks denote suggested comparisons. Detailed explanations of the rationales for each comparison may be found in the Report to AHRQ on Baseline Measures, Inventory, and Recommendations.¹¹
- Other comparisons are feasible, but the ones shown in the matrix are anticipated to be among the most useful as tools designed to gain a better understanding of how differences in sample and surveillance methodology translate to differences in observed HAI rates.

Exhibit 16: Data Triangulation Matrix

	NHSN	EIP/ABCs	MPSMS	HCUP	NHDS	MedPAR	MAX
NHSN				✓			
EIP/ABCs			✓	✓			
MPSMS						✓	
IICUP					✓	✓	✓
NHDS						✓	✓
MedPAR							✓
MAX							